

COA 43252-8-II

No. 86224-9

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY
CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN,
Appellants,

v.

CITY OF PORT ANGELES, and CITY OF FORKS,
Respondents.

REPLY BRIEF OF APPELLANTS/CROSS RESPONDENTS

Gerald B. Steel WSBA # 31084
Gerald B. Steel, PE
Attorneys for all Appellants/
Cross Respondents

7303 Young Rd. NW
Olympia, WA 98502
(360) 867-1166
(360) 867-1166 FAX
geraldsteel@yahoo.com

CLERK

BY RONALD R. CARPENTER

2012 FEB 21 P 4: 14

STATE OF WASHINGTON

RECEIVED
SUPREME COURT

STATE OF WASHINGTON

TABLE OF CONTENTS

	Page
I. <u>INTRODUCTION</u>	1
A. <u>The City Brief Makes Two Major Errors</u>	1
B. <u>Drugs Are Designated By Definition By Congress In The Federal Food, Drug, And Cosmetic Act (“FFDCA”)</u>	1
1. <u>Prescription and nonprescription drugs are designated by definition by Congress in the FFDCA</u>	1
2. <u>Unapproved drugs exist but they are not allowed to be legally marketed in the U.S.</u>	2
3. <u>Unapproved drugs are still drugs even if they are unknown to the FDA</u>	2
4. <u>FDA regulatory enforcement is discretionary</u>	2
5. <u>Whether FDA has exercised its drug authority over the Cities’ bulk fluoride products, and/or fluoridated waters is irrelevant to the issue of whether these fluorides and fluoridated waters are federal drugs and prescription drugs as designated by Congress</u>	3
C. <u>WAC 246-883-020(2) Is Not The Controlling Definition For “Legend Drugs” In Washington State</u>	4
II. <u>RESPONSE TO CROSS/APPELLANTS’ ISSUES PERTAINING TO ASSIGNMENTS OF ERROR</u>	6
A. <u>Reply To Cities’ Response To Citizens’ Assignments Of Error And Citizens’ Issues</u>	6
1. <u>Citizens brought this case because it involves fundamental issues of broad public import and did not bring this case for political purposes</u>	6
2. <u>This case is in furtherance of the policy of this state</u>	6
3. <u>This case presents only one claim of a violation by the Cities</u>	7

4.	<u>If the Cities are found in violation of the one claim brought in this case, then enforcement is by seizure if the fluorides are legend drugs or by surrender to and destruction by the state board of pharmacy If they are not legend drugs</u>	8
5.	<u>The Cities' reformulation of Citizens' Issues should not guide this Court's review</u>	9
B.	<u>Response To The Cities' Issues Pertaining To The Cities' Assignments Of Error</u>	9
1.	<u>Cross-Appeal Issue</u>	10
III.	<u>RESPONSE TO CROSS/APPELLANTS' STATEMENT OF THE CASE</u>	10
A.	<u>Our Water-Our Choice! And Protect Our Waters Are Not In Privity With Citizens</u>	10
B.	<u>EPA Does Not Regulate Public Drinking Water Additives And FDA Retains Authority To Regulate Public Drinking Water And Additives As Drugs If They Meet The Definition In 21 U.S.C. 321(g)(1)(B)</u>	10
C.	<u>The SDWA Does Not Regulate Or Give EPA Authority To Regulate Water Additives</u>	11
D.	<u>The Board Of Health Has Authority To Regulate The Safety Of Public Drinking Water But Does Not Have Authority To Regulate The Manufacture, Distribution, And Safety Of Drugs</u>	12
E.	<u>This Court Should Resolve Whether The Cities' Bulk Fluoride Additives Or Fluoride Additives In The Cities' Drinking Waters (Fluoridated Waters) Are Drugs And/Or Prescription Drugs Under Federal And State Law And/Or Legend Drugs Under Ch. 69.41 RCW</u>	13
F.	<u>This Court Should Resolve Whether Designating A Substance As A Drug And/Or A Prescription Drug Is Made By The FFDCA Or The FDA</u>	14

G.	<u>This Court Should Resolve Whether Federal Prescription Drugs Must Be Listed In The Red Book In Order To Be Legend Drugs Under RCW 69.41.010(12) And, If So, Whether The Cities’ Bulk Fluorides And Added Fluorides In Drinking Waters Are Adequately “Listed” In The Red Book For This Civil Action</u>	15
H.	<u>Citizens Did Not Seek Amendment To Its Complaint To Avoid Dismissal But Instead To Have A Court Rule On Whether The Cities’ Bulk Fluorides and Fluorides Added To Drinking Water Are Drugs</u>	17
IV.	<u>ARGUMENT</u>	18
A.	<u>Standard Of Review</u>	18
1.	<u>Standard of review for CR 12(b)(6) and CR 12(c) motions</u>	18
2.	<u>Standard of review for Order Denying Motion to Amend Complaint</u>	18
3.	<u>Standard of review for argument that WAC 246-290-220(3) and WAC 246-290-460(2) and -(3)(b)(iv)(A) violate U.S. Const. Art. VI, cl. 2 (Supremacy Clause)</u>	18
4.	<u>Standard of review regarding new arguments being heard by the appellate court</u>	19
5.	<u>Standard of review of trial court’s denial of costs and attorney fees</u>	19
a.	Denial of costs and fees under RCW 4.84.185	20
b.	Denial of costs and fees under CR 11	21
6.	<u>Standard of review for sanctions under RAP 18.9(a)</u>	22
B.	<u>The Cities’ Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Federal Drugs And Federal Prescription Drugs</u>	22
1.	<u>Citizens has alleged as a fact that the FDA has made the determination that fluoride additives in drinking water are drugs and prescription drugs</u>	24

2.	<u>The SDWA regulates contaminants and does not regulate water additives except to control contaminants</u>	27
3.	<u>It is alleged as a fact that WAC 246-290-220(3) that regulates additives generally and WAC 246-290-460 that regulates fluoride additives are not related to the requirements of the SDWA</u>	28
4.	<u>The 1979 MOU was terminated when EPA gave “Notice” that it was terminating its commitment to FDA to create a federal regulatory drinking water additives program and terminating its commitment to FDA to continue an informal advisory drinking water additives program</u>	29
5.	<u>There is no caselaw where a substance or article was not found to be a drug when it met the definition in 21 U.S.C. 321(g)(1)(B)</u>	33
6.	<u>It is an issue of first impression for this Court as to whether fluoride additives are drugs and prescription drugs</u>	33
C.	<u>The Cities’ Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are State Drugs, State Prescription Drugs, State Legend Drugs, and State Legend Drugs under Ch. 69.41 RCW</u>	35
D.	<u>RCW 69.41.010(12) Provides That A Drug Is A Legend Drug Under Ch. 69.41 RCW If There Is Any State Law Or State Board Of Pharmacy Regulation That Makes The Drug A State Prescription Drug Or Restricts The Drug To Use By Practitioners Only</u>	36
1.	<u>Considering WAC 246-879-010(9) and WAC 246-883-020(2), all federal prescription drugs are legend drugs under RCW 69.41.010(12)</u>	37
E.	<u>It Is An Alleged Fact That The State Board Of Pharmacy Has Determined That Fluoride Water Additives (“Fluorides”) Are State Legend Drugs Under Ch. 69.41 RCW</u>	37
1.	<u>The state board of health considers it “self evident” that water fluoridation is to prevent tooth decay</u>	38

2.	<u>Citizens has alleged as a fact that the state board of pharmacy has made the determination that fluoridation substances in drinking water are legend drugs under Ch. 69.41 RCW</u>	39
F.	<u>More Detail On The Legislative History Of RCW 69.41.010(12)</u>	40
G.	<u>Pursuant To WAC 246-883-020(1), Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Legend Drugs Under Ch. 69.41 RCW</u>	42
H.	<u>Pursuant To WAC 246-883-020(2), Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Legend Drugs Under Ch. 69.41 RCW</u>	42
1.	<u>“Listed in the Red Book” should be liberally construed for civil seizure cases</u>	43
2.	<u>Powdered Sodium Fluoride in quantities above 1/4 pound is a listed product in the Red Book</u>	43
3.	<u>Fluorosilicic Acid in quantities above 3/4 pound should be considered to be an implied listing in the Red Book</u>	45
4.	<u>If the fluoridation substances are adequately listed in the Red Book, then these substances remain listed when added to water so the fluoride additives in water (fluoridated waters) remain a “listed” product in the Red Book</u>	46
I.	<u>The Cities Misinterpret The Doctrine Of Primary Jurisdiction</u>	47
J.	<u>Relief Requested</u>	48
1.	<u>Because, under the alleged facts, the Cities’ fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are legend drugs under Ch. 69.41 RCW, the trial court’s Order Granting Defendant Cities’ Motion to Dismiss should be reversed</u>	48
2.	<u>The trial court’s Order Denying Motion to Amend Complaint should be reversed</u>	48

3.	<u>The trial court’s denial of the Cities’ request for costs and fees under RCW 4.84.185 and CR 11 should be affirmed</u>	49
4.	<u>This Court should deny the Cities’ request for costs and reasonable attorney fees on appeal under RAP 18.9(a)</u>	49
5.	<u>Citizens should be awarded statutory attorney fees and costs pursuant to 4.84.020 and -.080</u>	49
V.	<u>CONCLUSION</u>	50
	CERTIFICATE OF SERVICE	51
	APPENDIX INDEX	52

TABLE OF AUTHORITIES

Table of Cases

Page	
21, 22	<u>Bryant v. Joseph Tree, Inc.</u> , 119 Wn.2d 210, 829 P.2d 1099 (1992)
19, 21	<u>Building Industry Ass'n of Washington v. McCarthy</u> , ____ Wn.App. ____, 218 P.3d 196 (2009)
22	<u>Cary v. Allstate Ins. Co.</u> , 130 Wn.2d 335, 922 P.2d 1335 (1996)
9, 10, 11, 12 28, 29, 33	<u>City of Port Angeles v. Our Water-Our Choice!</u> , 170 Wn.2d 1, 259 P.3d 589 (2010)
34, 35	<u>Coshow v. City of Escondido</u> , 132 Cal.App.4 th 687, 34 Cal.Rptr.3d 19, 34 (2005)
18	<u>Dave Robbins Construction Co. v. First American Title Co.</u> , 158 Wn. App. 895, 249 P.3d 625 (2010)
21	<u>Deja Vu-Everett-Federal Way, Inc. v. City of Federal Way</u> , 96 Wn.App. 255, 979 P.2d 464 (1999)
20	<u>Dix v. ICT Group Inc.</u> , 160, Wn.2d 826, 161 P.3d 1016 (2007)
23	<u>Dowell v. Tulsa</u> , 273 P.2d 859 (Ok. 1954)
19	<u>Entertainment Industry Coalition v. Tacoma-Pierce County Health Dept.</u> , 153 Wn.2d 657, 105 P.3d 985 (2005)
20	<u>Forster v. Pierce County</u> , 99 Wn.App. 168, 991 P.2d 687 (2000)
3	<u>Gadler v. United States</u> , 425 F.Supp. 244, (D.Minn. 1977)
43	<u>Go2net, Inc. v. Freeyellow.Com, Inc.</u> , 158 Wn.2d 247, 143 P.3d 590 (2006)
3	<u>Heckler v. Chaney</u> , 470 U.S. 821, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985)
21	<u>IBF, LLC v. Heuft</u> , 141 Wn.App. 624, 174 P.3d 95 (2007)

- 19 In re Detention of Young, 163 Wn.2d 684, 185 P.3d 1180 (2008)
- 20 In re Welfare of B.R.S.H., 141 Wn.App. 39, 169 P.3d 40 (2007)
- 2 Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352 (11th Cir. 2011)
- 23 Kraus v. City of Cleveland, 127 N.E.2d 609, (Ohio 1955)
- 9, 23, 33, 34 Kaul v. City of Chehalis, 45 Wn.2d 616, 277 P.2d 352 (1954)
- 19 Maynard Inv. Co. v. McCann, 77 Wn.2d 616, 465 P.2d 657 (1970)
- 48 Northwest Ecosystem Alliance v. Washington Dept. of Ecology, 104 Wn.App. 901, 17 P.3d 697 (2001)
- 48 Rabon v. City of Seattle, 107 Wn.App. 734, 34 P.3d 821 (2001)
- 26, 40 Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S.Ct. 999 (2008)
- 19 Roberson v. Perez, 156 Wn.2d 33, 123 P.3d 844 (2005)
- 19 Skimming v. Boxer, 119 Wn.App. 748, 82 P.3d 707 (2004)
- 20 State ex rel. Quick-Ruben v. Verharen, 136 Wn.2d 888, 969 P.2d 64 (1998)
- 22 Tiffany Family Trust Corp. v. City of Kent, 155 Wn.2d 225, 119 P.3d 325 (2005)
- 20 Timson v. Pierce County Fire Dist. 15, 136 Wn.App. 376, 149 P.3d 427 (2006)
- 23 United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969)
- 23 United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734 (2nd Cir. 1969)
- 33 United States v. Bowen, 172 F.3d 682, (9th Cir. 1999)
- 20 Washington State Physician Ins. Exch. & Ass'n v. Fisons Corp., 122 Wn.2d 299, 858 P.2d 1054 (1993)

RCW

49, 50	4.84.020
49, 50	4.84.080
10, 19, 20, 49, 50	4.84.185
13, 41	18.64
12, 29	18.64.005(7)
35	18.64.011(11)(b)
5, 14, 36, 41, 42	18.64.011(14)
42	18.64.310(4)
41	18.64.460(4)
38	34.05.330(1)
38	34.05.330(3)
12, 28	43.20.050(2)(a)
39	68.38.010
39	68.38.020
13	69.04
35	69.04.009(2)
4, 7, 13, 35, 36, 37, 38, 39, 40, 41, 42, 43, 45, 48	69.41
34, 39, 40	69.41.010
40, 41	Former 69.41.010(8)
35	69.41.010(9)(b)
4	69.41.010(5)

41	69.41.010(7)
41	69.41.010(8)
4, 5, 8, 14, 15, 16, 17, 26, 36, 37, 40, 41, 42, 46, 50	69.41.010(12)
40	69.41.030(2)
40	69.41.060
42	69.41.075
7, 44, 47	69.41.100
40	69.41.230

U.S.C.

1	21 U.S.C. 301 et seq.
27	21 U.S.C. 321(f)
1, 2, 3, 27	21 U.S.C. 321(g)(1)
44	21 U.S.C. 321(g)(1)(A)
3, 8, 10, 11, 17, 22, 23, 24, 28, 33, 35	21 U.S.C. 321(g)(1)(B)
24	21 U.S.C. 321(ff)(1)(B)
1, 2, 17, 24	21 U.S.C. 353(b)(1)
1	21 U.S.C. 353(f)(1)(A)
2	21 U.S.C. 355(a)
2	21 U.S.C. 360bbb-3(a)(2)
1	21 U.S.C. 379r(a)(1)
27	21 U.S.C. 393(b)(2)(A)
2, 27	21 U.S.C. 393(b)(2)(B)

1	21 U.S.C. 802(45)(A)(ii)
1	21 U.S.C. 829(a)
28	42 U.S.C. 300f et seq.
28	42 U.S.C. 300g-1(b)(11)

CFR

24	Former CFR 250.203
16, 26	21 CFR 355.1 et seq.
26	21 CFR 355.60

Court Rules

10, 19, 21, 22 49, 50	CR 11
18, 24, 26, 39 40	CR 12(b)(6)
18, 24, 26, 39 40	CR 12(c)
22	RAP 2.2
19	RAP 2.5(a)
22, 49, 50	RAP 18.9(a)

WAC

12, 18, 28	246-290-220(3)
12, 28, 38	246-290-460
18, 26	246-290-460(2)
18	246-290-460(3)(b)(iv)(A)
5	246-867-010

40, 46	246-879-010(9)
5	246-869
5	246-878
5	246-879
5	246-879-010
41	246-879-010(8)
4, 5, 35, 36, 37, 42	246-879-010(9)
5	246-881
39, 42	246-883-020
42	246-883-020(1)
1, 4, 5, 15, 37, 42, 43, 46	246-883-020(2)
7, 8, 43	246-899-040(1)
8	246-899-040(2)

I. INTRODUCTION

A. The City Brief Makes Two Major Errors

The Brief of Respondents (“City Br.”) makes two major errors: first it erroneously claims that the FDA (instead of Congress) designates drugs and prescription drugs¹; and second, it erroneously claims that WAC 246-883-020(2) is the controlling definition for “legend drugs” in Washington State.²

B. Drugs Are Designated By Definition By Congress In The Federal Food, Drug, And Cosmetic Act (“FFDCA”)

1. Prescription and nonprescription drugs are designated by definition by Congress in the FFDCA

The designation of drugs is done by definition by Congress and not by the FDA. (21 U.S.C. 321(g)(1); A 21 to Citizens’ Br. (“A 21”).)³ Congress designates drugs as either prescription or nonprescription (“over the counter”). Prescription drugs are designated by 21 U.S.C. 353(b)(1) (R 1 hereto) for people and by 21 U.S.C. 353(f)(1)(A) for animals.⁴ Nonprescription drugs are drugs that are not subject to the requirements of said Sec. 353(b)(1) or 353(f)(1)(A). (21 U.S.C. 379r(a)(1); R 2 hereto.)⁵

¹ City Br. at 7-8 (a state legend drug must be “designated as a prescription drug (a legend drug) by the FDA”); 9 (“the U.S. Food and Drug Administration (‘FDA’) must classify the substance as a legend drug”); 15 (“**Fluoridation Additives Are Legend Drugs Only If the FDA Has Designated Them a Legend Drug**”); 16 (“**FDA Has Not Designated Public Drinking Water or Bulk Fluoridation Additives as Legend Drugs**”); 22 (“the Cities fluoridated drinking water and bulk additives must **actually be** ‘designated as legend drugs under federal law’ by the FDA”); 22, Note 33 (“Under federal law, FDA must designate a substance as requiring a prescription”); 27 (Washington legend drugs must “be designated federal legend drugs by the FDA”); 27 (“to be a legend drug, a substance must be designated (by FDA) as a federal legend drug”); and 43 (Washington legend drugs require “FDA designation as a federal legend drug”). (All emphasis in original.)

² City Br. at 22, Note 33 (“Under State law, the Board of Pharmacy definition in WAC 246-883-020(2) controls what is a legend drug”); 10, 15, 43, and 44.

³ This brief uses the same conventions as the Brief of Appellants: Report of Proceedings is “RP”; Clerk’s Papers is “CP”; and Appendix to Brief of Appellants is “A”.

⁴ “R 1 hereto” refers to page R 1 in the Appendix to this brief.

⁵ See 21 U.S.C. 829(a) (“a prescription drug [is] determined under the [FFDCA]”); see also 21 U.S.C. 802(45)(A)(ii) (“may be marketed or distributed lawfully in the United States under the [FFDCA] (21 U.S.C. 301 et seq.) as a nonprescription drug.”)

2. **Unapproved drugs exist but they are not allowed to be legally marketed in the U.S.**

Although not responsible for the designation of drugs, the FDA is responsible for “ensuring” that “drugs are safe and effective.” (21 U.S.C. 393(b)(2)(B); R 3 hereto.) Congress has provided that no drug may be legally marketed in the U.S., unless the drug is approved by the FDA as safe and effective for some specific approved use.⁶ (*Id.*; *see* 21 U.S.C. 355(a) (R 4 hereto); *see also* 21 U.S.C. 360bbb-3(a)(2).) Drugs may be FDA approved, unapproved or unapproved for a specific use. (21 U.S.C. 360bbb-3(a)(2)).

3. **Unapproved drugs are still drugs even if they are unknown to the FDA**

Unapproved drugs include those that have not been evaluated and approved by the FDA. (CP 138.) But unapproved drugs unknown to the FDA are still drugs. Therefore it must be the definition in 21 U.S.C. 321(g)(1) that designates these substances as drugs. (A 21.) Congress designates drugs and not the FDA. Similarly, it must be the definition in 21 U.S.C. 353(b)(1) that designates whether these drugs are prescription drugs for people. (R 1 hereto.) Congress designates prescription drugs and not the FDA.

4. **FDA regulatory enforcement is discretionary**

Congress has designated drugs and prescription drugs in the FDCA. (Brief of Appellants at 12-25 and 34-35.) The Courts have authority to interpret the FDCA and determine if specific substances are drugs and

⁶ The practice of **prescribing** an approved drug for an unapproved use is legal and commonplace. Ironworkers Local Union 68 v. AstraZeneca Pharmaceuticals, LP, 634 F.3d 1352, 1356 and n. 4 (11th Cir. 2011). It is illegal for a manufacturer to promote a drug for an unapproved use. *Id.* at 1356, n. 5.

prescription drugs and determine if either a drug or a specific use is unapproved.⁷ The FDA has discretionary regulatory enforcement authority over drugs. (*Heckler v. Chaney*, 470 U.S. 821, 835, 105 S.Ct. 1649, 84 L.Ed.2d 714 (1985).) A court cannot require the FDA to exercise its regulatory enforcement authority. (*Id.* at 837-38.)

5. **Whether FDA has exercised its drug authority over the Cities' bulk fluoride products, and/or fluoridated waters is irrelevant to the issue of whether these fluorides and fluoridated waters are federal drugs and prescription drugs as designated by Congress**

In March of 2011, the FDA took action against certain unapproved prescription cough, cold, and allergy drugs as the “17th action on a drug class as part of FDA’s Unapproved Drugs Initiative.” (76 FR 11794-98 (2011) - R 5-9 hereto.) Under this Initiative, the FDA has not yet gotten to enforcement action on unapproved fluoride anticaries drugs and uses.⁸ In 2000, the FDA reported that it had not yet completed its review of effectiveness for unapproved fluoride-containing drugs. (CP 352-53.)

Lack of enforcement by the FDA against unapproved fluoride drugs and uses is irrelevant to Citizens’ Issues No. 1 and 4 before this Court which ask, whether under any facts that could possibly be established, can the Cities’ bulk fluoride additives and/or fluoride additives in public drinking waters (fluoridated waters) be drugs pursuant to 21 U.S.C. 321(g)(1) and prescription drugs under federal law and regulation. (Brief of Appellants at

⁷ See *Gadler v. United States*, 425 F.Supp. 244, 246-47 (D.Minn. 1977) citing a number of cases where the Courts have found that “even the most commonly ingested foods and liquids are ‘drugs’ within the meaning of the [FFDC] Act if their intended use falls within the definition of s 321(g)(1)(B).” Sec. 321(g)(1)(B) is provided in A 21.

⁸ CP 255-56 provides link showing no action yet on unapproved fluoride anticaries drugs. <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/SelectedEnforcementActionsonUnapprovedDrugs/ucm238675.htm>

4-5.) Citizens have established that the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs and prescription drugs under federal law and regulation. (Brief of Appellants at 2-8, 12-27, and 32-35.)

C. **WAC 246-883-020(2) Is Not The Controlling Definition For "Legend Drugs" In Washington State**

The Cities' Brief erroneously claims that a regulation, WAC 246-883-020(2), is the controlling definition for legend drugs. (City Br. at 22 n.33, 10, 15, 43 and 44.) The actual controlling definitions for state "legend drugs" are statutes and not regulations. (Brief of Appellants at 35-38.)

Under Chapter 69.41 RCW:

"Legend drugs" means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.

(RCW 69.41.010(12) - Brief of Appellants at 36.) A prescription drug is only dispensed on prescription. (RCW 69.41.010(5).) Therefore a drug that is made a prescription drug by a state board of pharmacy regulation is a legend drug under Chapter 69.41 RCW.

Every federal prescription drug is made a state prescription drug by a state board of pharmacy regulation:

"Prescription drug" means any drug required by state or federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(WAC 246-879-010(9).) Therefore every federal prescription drug is a legend drug under RCW 69.41.010(12) and WAC 246-879-010(9). This

interpretation is consistent with RCW 18.64.011(14) which also defines state legend drugs as including federal prescription drugs.

The Cities' response to the above argument is without merit. (City Br. at 22, Note 33.) First, the Cities argue WAC 246-879-010(9) is in a chapter governing wholesalers. (*Id.*) But WAC 246-879-010 does not have a preface that states these definitions apply only to one chapter and so it is a general definition of the board of pharmacy.⁹ Also, "prescription drug" is not defined in any other board of pharmacy regulation but the term is found in four board of pharmacy chapters: Chapters 869, 878, 879, and 881 of Title 246 WAC.

The Cities' second response is that under federal law, FDA must designate a substance as requiring a prescription. (City Br. at 22, Note 33.) This major error of the Cities is addressed *supra* at 1-4.

The Cities' final response is that WAC 246-883-020(2) is controlling. (City Br. at 22, Note 33.) But statutes and not regulations are controlling. (*Supra* at 4-5.) This subject is discussed further *infra* at 35-47. Because the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are prescription drugs under federal law and regulation, they are legend drugs under RCW 69.41.010(12) and the trial court's contrary conclusions and orders (CP 8-10 and 12-13) should be reversed.

⁹ When a definitions section applies only to one chapter, the board of pharmacy so states: e.g. WAC 246-867-010 ("Definitions - For the purpose of this chapter")

II. RESPONSE TO CROSS/APPELLANTS' ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

A. Reply To Cities' Response To Citizens' Assignments Of Error And Citizens' Issues

1. Citizens brought this case because it involves fundamental issues of broad public import and did not bring this case for political purposes

Citizens object to the Cities' statement that Citizens' assignments of error are "intentionally argumentative for political purposes." (*See* City Br. at 3.) Citizens deny that its assignments of error or issues are argumentative or for political purposes or that the instant case is brought for political purposes. The City Br. at 1 (and 37, 40, and 43) argues that Citizens bring this case to "abuse the judicial system" using it "for political, not legal, purposes." This argument is unfounded.

Instead, Citizens bring this case because it involves fundamental and urgent issues of broad public import which require prompt and ultimate determination. (Statement of Grounds for Direct Review at 11-15.) About half of the people in Washington State are receiving waters with fluoride substances added to prevent dental caries disease and this includes nearly all of the people in the Cities of Forks and Port Angeles. (*Id.*) In our issues, we are asking this Court to find that the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs and prescription drugs. Our arguments are well grounded in fact and law and certainly are not "meritless" as the Cities contend. (*See* City Br. at 1).

2. This case is in furtherance of the policy of this state

It is the policy of this state to ensure that drug products meet high drug quality standards and are safe and therapeutically effective.

The legislature hereby declares it to be the policy of the state that its citizens receive safe and therapeutically effective drug products at the most reasonable cost consistent with high drug quality standards.

(RCW 69.41.100.) As a preliminary matter, to implement this policy, it is necessary that courts determine what substances are drugs when a request is made. Note that this policy, which appears in Ch. 69.41 RCW, applies to all drugs including prescription drugs. Today, the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are not being subjected to "high drug quality standards" and have not been FDA approved as "safe and therapeutically effective drug products." The FDA's Unapproved Drugs Initiative also seeks to remove unapproved drugs from the market "to reduce consumer exposure to drugs that are not proven safe, effective, and of high quality." (CP 255.)

If this Court agrees with Citizens that the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs, then the FDA and the state board of pharmacy will know that they can safely take enforcement action.

3. **This case presents only one claim of a violation by the Cities**

The Complaint in the instant case brings a single claim of a violation by the Cities. This claim states:

The bulk fluoride products stored by the Cities at their water fluoridation facilities are in violation of RCW 69.41 implementing regulation, WAC 246-899-040(1), [CP 266], which requires drug products stored at the premises of a drug manufacturer or distributor to have an approved NDA or ANDA which the bulk fluoride products do not have.

(CP 261, Para. 13.) The Complaint alleges no other claims of violations by the Cities. The Complaint requests relief by asking the trial court to find probable cause that a warrant should issue to seize the Cities' fluoride additives and fluoridation equipment. (CP 263, Para. 24.) The warrant should issue if there is probable cause to believe that the fluoride additives alone and/or as added to the Cities' waters are legend drugs. (See CP 260-61, Para 8, 10, 12, and 14.) The Complaint requests "such other relief that this Court deems just and equitable." (CP 264.)

The Brief of Appellants, as supplemented by this brief, provides rational and compelling argument, well-grounded in fact, that the Cities' fluorides, both in bulk form and when distributed in public drinking waters, are drugs by definition under federal and state statute despite the lagging enforcement by the FDA and the state board of pharmacy.

4. **If the Cities are found in violation of the one claim brought in this case, then enforcement is by seizure if the fluorides are legend drugs or by surrender to and destruction by the state board of pharmacy if they are not legend drugs**

If the Cities are found in violation of WAC 246-899-040(1) because their bulk fluorides and/or fluorides added to drinking waters are [unapproved] drugs under 21 U.S.C. 321(g)(1)(B), then relief should be given by a warrant for seizure if even one of these drugs is a legend drug under RCW 69.41.010(12). If none of these drugs are legend drugs under RCW 69.41.010(12), then they are still subject to surrender to, and destruction by, the state board of pharmacy under WAC 246-899-040(2). (CP 266.) Therefore it is important to Citizens and to many others around the state that this Court determine if the Cities' bulk fluoride additives and fluoride

additives in public drinking waters (fluoridated waters) are drugs and/or prescription drugs.

5. The Cities' reformulation of Citizens' Issues should not guide this Court's review

The City Br. at 3 and 10-11 claims that the Washington Supreme Court “has determined fluoridated drinking water is not a drug.” The Brief of Appellants at 1 claims that the summary rejection in Kaul v. City of Chehalis, 45 Wn.2d 616, 625, 277 P.2d 352 (1954) of a claim that the City was selling drugs was just dicta. The Brief of Appellants at 1 claims the majority in City of Port Angeles v. Our Water-Our Choice!, 170 Wn.2d 1, 259 P.3d 589, 594, n. 6 (2010) “did not reach the issue of whether fluoride and fluoridated waters are drugs.”

Sections 2.3.1 to 2.3.4 of the City Br. at 3-4, present the Cities' proposed Issues based on Citizens' assignments of error. These sections inappropriately include statements that are represented as truths by the Cities but which are contested in Citizens' assignments of error. Also each of these sections frame an issue and then inappropriately instruct the Court how the issue must be decided. It is up to the Court, and not to the Cities, to determine how each issue will be decided.

B. Response To The Cities' Issues Pertaining To The Cities' Assignments Of Error

The Cities propose four issues pertaining to the Cities' assignments of error. (City Br. at 2-3.) These four issues are stated in an argumentative manner and inappropriately instruct the Court as to how the issues must be decided. These issues can be restated in a single issue as follows:

1. **Cross-Appeal Issue**

Should the trial court's denial of the Cities' request for costs and fees under RCW 4.84.185 and CR 11 be affirmed or reversed? (Cities' Errors 1 and 2.)

III. **RESPONSE TO CROSS/APPELLANTS' STATEMENT OF THE CASE**

A. **Our Water-Our Choice! And Protect Our Waters Are Not In Privity With Citizens**

The Cities state that Appellants ("Citizens") are "related" to Our Water - Our Choice! and Protect Our Waters, who were the Petitioners in City of Port Angeles (City Br. at 5) and that Appellants participated in that case (City Br. at 44). This is not true. Our Water - Our Choice! and Protect Our Waters are independent political action committees that are not in privity with Citizens.

B. **EPA Does Not Regulate Public Drinking Water Additives And FDA Retains Authority To Regulate Public Drinking Water And Additives As Drugs If They Meet The Definition In 21 U.S.C. 321(g)(1)(B)**

The Cities cite to City of Port Angeles at 6 (n. 1) for the proposition that EPA does regulate public drinking water additives and that the FDA does not regulate public drinking water systems or additives. (City Br. at 6.) This is not an accurate characterization of the referenced citation. The referenced citation only states that "the Environmental Protection Agency, not the FDA, regulates public drinking water systems" and the citation references the terminated 1979 MOU between EPA and FDA ("1979 MOU"). The Cities misstate City of Port Angeles because that case did not find that EPA regulates public drinking water additives. There can be no doubt today that

the EPA does not regulate public drinking water additives and that the FDA does retain authority to regulate public drinking water and additives as drugs if they meet the definition in 21 U.S.C. 321(g)(1)(B).

The Brief of Appellants at 2, states that Note 1 in City of Port Angeles is dicta. The Brief of Appellants at 13-14 and 21-24 discusses the 1979 MOU in more detail and discusses later notices from EPA that Citizens claim resulted in the termination of the 1979 MOU. The Brief of Appellants at 21-24 describes how the 1979 MOU was intended only to reach agreement as to how FDA would exercise its legal authority over public drinking water as a food, and how the 1979 MOU did not intend to affect how FDA would exercise its legal authority over public drinking water and water additives when these substances are drugs under 21 U.S.C. 321(g)(1)(B).

C. **The SDWA Does Not Regulate Or Give EPA Authority To Regulate Water Additives**

The U.S. Safe Drinking Water Act (“SDWA”) sets maximum levels of contaminants in public drinking water before enforcement is authorized. The City Br. at 6 cites to City of Port Angeles at 8 for the proposition that the SDWA regulates all public drinking water systems in the United States. This is true. But the SDWA does not regulate or give EPA authority to regulate water additives. (*Supra* at 8-9; *infra* at 10-12 and 27-28.) There is no valid support for the statement made by the City Br. at 1 that “federal law expressly allow[s], and strictly regulate[s] fluoridation.”

The City Br. at 7 cites to City of Port Angeles at 9 for the proposition that under the SDWA, 40 chemicals may be added to public water supplies, including fluoride. Later in this brief (*infra* at 28-33) Citizens will allege as

a fact that it can prove, that the Board of Health rule that regulates public drinking water additives (WAC 246-290-220(3)) and the Board of Health rule that regulates fluoride additives (WAC 246-290-460) are not related to the requirements of the Federal SDWA, that EPA regulates.

D. The Board Of Health Has Authority To Regulate The Safety Of Public Drinking Water But Does Not Have Authority To Regulate The Manufacture, Distribution, And Safety Of Drugs

The City Br. at 6 cites to City of Port Angeles at 8 for a statement that the Department of Health and Board of Health are given the power and duty to regulate the health and safety of drinking water. (City Br. at 6.) The cited language in City of Port Angeles at 8 actually states that the Department of Health has this power, but then the City of Port Angeles Court cites to RCW 43.20.050(2)(a) (A 27) which explicitly gives this power only to the Board of Health.¹⁰ When dealing with fluorides and fluoridated waters, it is important to note that the legislature gives the power to regulate the manufacture and distribution of drugs for protection and promotion of the public health, safety, and welfare to the state board of pharmacy. (RCW 18.64.005(7) (A 30).) The Board of Health has authority to regulate the safety of public drinking water but does not have authority to regulate the manufacture, distribution, and safety of drugs.

¹⁰ The Brief of Appellants at 32, Note 7 describes the difference between the Board of Health and the Department of Health. The block quote in the City Br. at 36 highlights the error made by the City of Port Angeles Court and all references on that page to the Department of Health should be references to the Board of Health. The said block quote is also in err because while the Board of Health regulations allow additives, it is a fact alleged by Citizens and confirmed by the EPA that these additives are not regulated by the EPA or the SDWA. (*Supra* at 11-12; *infra* at 28-33.)

E. **This Court Should Resolve Whether The Cities' Bulk Fluoride Additives Or Fluoride Additives In The Cities' Drinking Waters (Fluoridated Waters) Are Drugs And/Or Prescription Drugs Under Federal And State Law And/Or Legend Drugs Under Ch. 69.41 RCW**

The City Br. at 7 states that prescription drugs are regulated by the state board of pharmacy and Ch. 69.41 RCW. Actually, prescription drugs are primarily regulated by the FDCA and by Chapters 18.64, 69.04, 69.41, and other chapters of the RCW along with implementing regulations of the FDA and the state board of pharmacy.

To be legally marketed in the U.S. all drugs must be approved by the FDA. (*Supra* at 2.) The Cities do not claim that their bulk fluoride additives or fluoride additives in public drinking waters (fluoridated waters) are approved by the FDA. Instead, the Cities claim that these additives and waters are not drugs under state and federal law, are not prescription drugs under state and federal law, and are not legend drugs under Ch. 69.41 RCW. This Court should resolve these issues.

In particular, if this Court rules that the Cities' bulk fluoride additives and/or fluoride additives in public drinking waters (fluoridated waters) are or can be drugs under implied or alleged facts, then this Court should find that the trial court abused discretion when it issued its Order Denying Motion to Amend Complaint based on a ruling that the amendment (asking for a declaration that these additives are drugs) would be futile. (CP 12-13.)

The Cities express concern that if these substances and waters are found to be legend drugs it could close down the Cities' fluoridation programs. (City Br. at 7.) If this Court finds that facts can possibly exist such that these substances and waters may be legend drugs under Ch. 69.41

RCW, the Cities are correct that it will likely result in seizure in place of the Cities' fluoridation additives and suspension of the Cities' fluoridation programs. If the fluoridation programs are suspended, the Cities would be able to resume their programs if approvals from the FDA are requested and granted.

The Cities also claim there would be seizure of all of the Cities' public drinking waters. (City Br. at 7.) While the Complaint does request seizure in-place of the fluoridation equipment, the Complaint does not request seizure of the Cities' public drinking waters and, in fact, specifically requests "that source water will continue to flow to the City's customers" during and after the seizure. (CP 263-64.)

F. **This Court Should Resolve Whether Designating A Substance As A Drug And/Or A Prescription Drug Is Made By The FFDC A Or The FDA**

The City Br. at 7-8 states that the trial court applied "clear" state board of pharmacy regulations to determine that the fluoridation substances and water containing those substances could not be legend drugs. The laws to be interpreted are RCW 69.41.010(12) and RCW 18.64.011(14). The parties agree on the facts of this case that to be a legend drug in Washington state, the substance must be a prescription drug under federal law. The parties disagree as to whether designating a substances as a drug and/or a prescription drug is made by the FFDC A (Citizens' interpretation) or the FDA (Cities and trial court's interpretation). This Court should resolve this issue.

G. **This Court Should Resolve Whether Federal Prescription Drugs Must Be Listed In The Red Book In Order To Be Legend Drugs Under RCW 69.41.010(12) And, If So, Whether The Cities' Bulk Fluorides And Added Fluorides In Drinking Waters Are Adequately "Listed" In The Red Book For This Civil Action**

Citizens claim that if the Cities' fluorides and fluoridated waters are federal prescription drugs, that is sufficient to make them legend drugs under RCW 69.41.010(12). (*Supra* at 4-5; Brief of Appellants at 34-37; *infra* at 35-37.) The Cities and trial court rely only on WAC 246-883-020(2) and conclude that to be a legend drug under RCW 69.41.010(12), the drug also must be "listed" as a Rx [prescription] drug in the 2009 Drug Topics Red Book ("Red Book"). (CP 8, Para. 6.) The Cities and trial court conclude as a matter of law (interpreting the ambiguous word "listed") that the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are not "listed" in the Red Book. (CP 9, Para. 8).

The parties agree that the City of Forks' bulk fluoride additive is sodium fluoride and the City of Port Angeles' bulk fluoride additive is fluorosilicic acid. The Red Book lists sodium fluoride as a prescription drug with typical minium package sizes of 100 to 125 gm (about 1/4 pound) for various manufacturers. (CP 373-74; R 14-15; Appellants' Brief at 38.) The City uses other manufacturers and 50 pound packages. (CP 324-26.) Citizens claim that listing of the drug's name, sodium fluoride powder (for various quantities over 1/4 pound), is all that is necessary to qualify the City's sodium fluoride as being "listed" in the Red Book. (Appellants' Brief at 37-38.) The Cities and trial court do not agree. (CP 9, Para. 8). This Court should decide if "listed" in the Red Book is a requirement to be a legend drug

under RCW 69.41.010(12) and if it is, then is the drug sodium fluoride powder (in quantities over 1/4 pound) adequately listed.

The parties agree that public drinking water is not listed as a prescription drug in the Red Book. But Citizens claim that if the listed prescription drug sodium fluoride is distributed to the public in public drinking water, the sodium fluoride remains a listed prescription drug in the water unless the mixture becomes an over-the-counter drug. (Appellants' Brief at 38; *infra* at 26 and 33.) Citizens claim that the drug "sodium fluoride in public drinking water" at about 1 ppm fluoride ion concentration is not an over-the-counter product because this product does not meet the anticaries monograph conditions in 21 CFR 355.1 et seq. (*Infra* at 25, n. 12; Appellants' Brief at 34-35.)

Citizens claim that the active ingredient in all fluoride anticaries products is fluoride ions and that, under ANSI/NSF Standard 60, the City of Port Angeles fluoride (fluorosilicic acid) is approved as a substitute for sodium fluoride and adjusted in dose to provide the same amount of the active ingredient fluoride ions in drinking water. (Appellants' Brief at 38; CP 122-23; *infra* at 45-46.) Citizens claim that the listing in the Red Book of fluorosilicic acid in bulk quantities is implied because it is a substitute drug for sodium fluoride to supply the same amount of the active ingredient, fluoride ions. *Id.* The Cities and the trial court conclude that being "listed" in the Red Book is a requirement to be a legend drug and the Cities' bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are not "listed." (CP 8-9; City Br. at 8.)

H. Citizens Did Not Seek Amendment To Its Complaint To Avoid Dismissal But Instead To Have A Court Rule On Whether The Cities' Bulk Fluorides and Fluorides Added To Drinking Water Are Drugs

The City Br. at 8 and 31 states that Citizens filed a motion “on the eve of the hearing” to amend their Complaint in “an attempt to avoid dismissal.” This motion was timely-filed and personally served on the Cities a week before the scheduled hearing in compliance with standard motion practice rules and was not filed “on the eve of the hearing.” In briefing its Response to the Cities’ Motion to Dismiss, Citizens argued that under the alleged facts, the Cities’ bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) were drugs under 21 U.S.C. 321(g)(1)(B) and prescription drugs under 21 U.S.C. 353(b)(1) but that seizure at Citizens request required the drugs to be legend drugs under RCW 69.41.010(12).

Citizens was concerned that the trial court might, as requested by the Cities, rule that the Cities’ bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) were required to be, and were not, “listed” in the Red Book. Citizens was concerned, that although it provided substantial briefing to demonstrate that the Cities’ bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs, the Court could ignore that briefing and not rule on the issue. It was for this reason that Citizens requested an amendment to the Complaint requesting the Court to declare that the Cities’ bulk fluoride additives and/or fluoride additives in public drinking waters (fluoridated waters) are drugs. (CP 203-04.)

The Cities are correct that the trial court dismissed Citizens motion as futile. (City Br. at 8.) But in doing so, the trial court gave Citizens the opportunity to prove that the amendment was not futile by proving to the Appellate Court that, under the alleged facts, the Cities' bulk fluoride additives and/or fluoride additives in public drinking waters (fluoridated waters) are drugs and that the trial court abused its discretion.

IV. ARGUMENT

A. Standard Of Review

1. Standard of review for CR 12(b)(6) and CR 12(c) motions

The Brief of Appellants at 9-10 gives the appropriate standard of review. The City Br. at 14 misstates the standard of review in citing to Dave Robbins Construction Co. v. First American Title Co., 158 Wn. App. 895, 896, 249 P.3d 625 (2010). First, the City Br. at 14 cites to headnotes on page 896, and not to the Division I Opinion. Second the Opinion actually states the question on review is whether “any facts could exist”(Dave Robbins at 903) and not just whether “facts will not support” (City Br. at 14).

2. Standard of review for Order Denying Motion to Amend Complaint

The Brief of Appellants at 10 gives the appropriate standard of review. The City Br. at 31 correctly adds that the Court may uphold the trial court on any ground substantiated by the record.

3. Standard of review for argument that WAC 246-290-220(3) and WAC 246-290-460(2) and -(3)(b)(iv)(A) violate U.S. Const. Art. VI, cl. 2 (Supremacy Clause)

The Brief of Appellants at 10-11 gives the appropriate standard of review. The City Br. does not claim otherwise.

4. **Standard of review regarding new arguments being heard by the appellate court**

RAP 2.5(a) makes it discretionary as to whether this Court will consider a new claim of error that was not raised before the trial court. (Roberson v. Perez, 156 Wn.2d 33, 39, 123 P.3d 844 (2005).) Courts frequently consider new claims on appeal when it affects the public interest.

Even though the matter was not raised below, the courts have frequently recognized that error may be considered for the first time on appeal where the matter in question affects the public interest. . . . When the question is of such a nature that the present welfare the people at large, or a substantial portion thereof, is involved, a departure from the general rule is warranted and the court is authorized in its discretion to direct its attention to the general welfare . . .

(Maynard Inv. Co. v. McCann, 77 Wn.2d 616, 622-23, 465 P.2d 657 (1970).)

5. **Standard of review of trial court's denial of costs and attorney fees**

The standard of review for attorney fees under RCW 4.84.185 and CR 11 is abuse of discretion. (Entertainment Industry Coalition v. Tacoma-Pierce County Health Dept., 153 Wn.2d 657, 666, 105 P.3d 985 (2005); Building Industry Ass'n of Washington v. McCarthy, ____ Wn.App. ____, 218 P.3d 196, 208 (2009).) A discretionary determination should not be disturbed on appeal except on a clear showing that the discretion was manifestly unreasonable, or exercised on untenable grounds, or for untenable reasons. (In re Detention of Young, 163 Wn.2d 684, 694, 185 P.3d 1180 (2008).) Only a decision to grant sanctions must be supported by findings in the record. (Skimming v. Boxer, 119 Wn.App. 748, 755, 82 P.3d 707 (2004).) No findings are required by a trial court that denies sanctions. (*Id.*) The Court may uphold the trial court on any ground substantiated by the record.

(*Supra* at 18.) The burden is on the movant to justify any request for sanctions. (Skimming at 754-55.)

a. Denial of costs and fees under RCW 4.84.185

A trial court has discretion to grant sanctions if it finds a lawsuit is frivolous. RCW 4.84.185. The lawsuit, as a whole, that is in its entirety, must be determined to be frivolous and to have been advanced without reasonable cause before an award of attorneys' fees may be made under the statute. (State ex rel. Quick-Ruben v. Verharen, 136 Wn.2d 888, 903, 969 P.2d 64 (1998).) If any of the claims asserted are not frivolous, then the action is not frivolous. (Forster v. Pierce County, 99 Wn.App. 168, 183-84, 991 P.2d 687 (2000).) A lawsuit is not frivolous when it is supported by any rational argument on the law and facts for any of its claims. (Forster at 183-84; Timson v. Pierce County Fire Dist. 15, 136 Wn.App. 376, 386, 149 P.3d 427 (2006).)

The City Br. at 41 concurs that the standard of review is abuse of discretion citing to Washington State Physician Ins. Exch. & Ass'n v. Fisons Corp., 12[sic 122] Wn.2d 299, 88[sic 858] P.2d 1054 (1993), a discovery sanction case not involving RCW 4.84.185. The City Br. at 41 states that the “trial court abuses discretion if it applies an incorrect legal standard or applies incorrect legal analysis” citing to Dix v. ICT Group Inc., 160, Wn.2[sic Wn.2d] 826, 833, 161 P.3d 1016 (2007) and In re Welfare of B.R.S.H., 141 Wn.App. 39, 56, 169 P.3d 40 (2007). Neither of these cases involved sanctions or a denial of sanctions. (*Id.*)

The City Br. at 42 cites to Deja Vu-Everett-Federal Way, Inc. v. City of Federal Way, 96 Wn.App. 255, 264, 979 P.2d 464 (1999) for the proposition that when a “claim” was barred it was abuse of discretion to deny attorney fees. In that case, the whole suit was barred by res judicata and there were no non-frivolous claims. (*Id.*)

b. Denial of costs and fees under CR 11

The City Br. at 45 misquotes CR 11. Below we provide an underline/strikeout copy of CR 11 to correct the Cities’ errors:

The signature of a party or of an attorney constitutes a certificate by the party or attorney that the party or attorney has read the pleading, motion, or legal memorandum; ~~and~~ and that to the best of the party's or attorney's knowledge, information, and belief, formed after ~~reasonable inquiry~~ an inquiry reasonable under the circumstances: (1) it is well grounded in fact ~~and~~; (2) is warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law or the establishment of new law; (3); ~~and that~~ it is not interposed for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation; and (4)

Complaints which are "grounded in fact" and "warranted by existing law or a good faith argument for the extension, modification, or reversal of existing law [or the establishment of new law]" are not "baseless" claims, and are therefore not the proper subject of CR 11 sanctions. (IBF, LLC v. Heuft, 141 Wn.App. 624, 637, 174 P.3d 95 (2007).) The appellate court reviews the record to see if the Complaint has a legal and factual basis. (Bryant v. Joseph Tree, Inc., 119 Wn.2d 210, 216, 829 P.2d 1099 (1992).) Abuse of discretion for CR 11 sanctions occurs only when no reasonable person would take the view that the trial court adopted. (Building Industry Ass'n of Washington v. McCarthy, ____ Wn.App. ____, 218 P.3d 196, 208 (2009).)

CR 11 sanctions have a potential chilling effect. And so the trial court should impose sanctions only when it is patently clear that a claim has absolutely no chance of success. The fact that a complaint does not prevail on the merits is not enough.

(*Id.* at 755.)

The rule is not intended to chill an attorney's enthusiasm or creativity in pursuing factual or legal theories. (Bryant v. Joseph Tree, Inc. at 219 (“Were vigorous advocacy to be chilled by the excessive use of sanctions, wrongs would go uncompensated.”))

6. Standard of review for sanctions under RAP 18.9(a)

RAP 18.9(a) gives an appellate court discretion to sanction a party or attorney for filing a frivolous appeal.

In determining whether an appeal is frivolous . . . we are guided by the following considerations: (1) A civil appellant has a right to appeal under RAP 2.2; (2) all doubts as to whether the appeal is frivolous should be resolved in favor of the appellant; (3) the record should be considered as a whole; (4) an appeal that is affirmed simply because the arguments are rejected is not frivolous; (5) an appeal is frivolous if there are no debatable issues upon which reasonable minds might differ, and it is so totally devoid of merit that there was no reasonable possibility of reversal.

(Tiffany Family Trust Corp. v. City of Kent, 155 Wn.2d 225, 241, 119 P.3d 325 (2005).) A case of first impression which presents debatable issues of substantial public importance is not frivolous. (Cary v. Allstate Ins. Co., 130 Wn.2d 335, 347-48, 922 P.2d 1335 (1996).)

B. The Cities’ Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Federal Drugs And Federal Prescription Drugs

The Brief of Appellants at 12-27 and 34-35 demonstrates that the Cities’ fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs under the controlling federal statute (21 U.S.C.

321(g)(1)(B)) that designates drugs as “ articles intended for use in the . . . prevention of disease.” Over the years since the 1950's, the Congress, the FDA, and the federal Supreme Court have taken actions that dictate that fluoride additives and fluoride additives in public drinking waters (fluoridated waters) be regulated as drugs under the FFDCA.

The Cities cite to state caselaw from the 1950s that should be found no longer to be good law with respect to the issue of whether the Cities' fluoride additives and fluoridated waters are drugs. These cases include Kaul v. Chehalis, 45 Wn.2d 616, 277 P.2d 352 (1955); Dowell v. Tulsa, 273 P.2d 859 (Ok. 1954) and Kraus v. City of Cleveland, 127 N.E.2d 609, (Ohio 1955). (City Br. at 33.) In the 1950s, the prevalent thinking was that vitamins and minerals were associated with foods and these substances should never be considered drugs. (See Dowell at 864 quoted in City Br. at 33.) In the 1950s, the FDA adopted a regulation stating that fluoridated water was not actionable under the FFDCA. (Brief of Appellants at 13-14.) But the legal framework has changed significantly since the 1950s.

In 1969, the U.S. Supreme Court ruled that 21 U.S.C. 321(g)(1)(B) should be applied “as broad as its literal language indicates.” (United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969); Brief of Appellants at 17-18.) Also in the 1960s it became settled law that the intended use of a product may be determined from any “relevant source.” (United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 739 (2nd Cir. 1969); see Brief of Appellants at 18-19.) Still, in 1979, the FDA still

considered fluoride additives in drinking water to be nutrients regulated as foods. (Brief of Appellants at 21 citing to CP 224 in the 1979 MOU.)¹¹

In 1994, Congress adopted the DSHEA which fully clarified Congressional intent that mineral additives including fluorides are drugs under 21 U.S.C. 321(g)(1)(B) if the intended use is to prevent disease. (Brief of Appellants at 14, and 19-20 citing to 21 U.S.C. 321(ff)(1)(B); A 22-23.) In response, in 1996, the FDA revoked 21 CFR 250.203 and made fluoridated water supplies actionable under the FFDCA. (Brief of Appellants at 13-14.)

1. **Citizens has alleged as a fact that the FDA has made the determination that fluoride additives in drinking water are drugs and prescription drugs**

Citizens argue that water fluoridation additives are federal drugs and federal prescription drugs pursuant to Congressional definitions in 21 U.S.C. 321(g)(1)(B) and 21 U.S.C. 353(b)(1). (Brief of Appellants at 16-25 and 34; *Supra* at 1-4.) But the Cities and the trial court have made a major error when they state that water fluoridation additives have not been determined to be drugs and prescription drugs by the FDA. (*Supra* at 1-4; CP 8-9.) Citizens has alleged as a fact that the FDA has determined that fluoridation products are drugs and prescription drugs. (Brief of Appellants at 14 (n.4); CP 259, Para. 5; CP 276, Para. 5; CP 281-82, Para. 7; CP 352-54.) The City Br. at 46 states it is “an indisputable fact that the FDA has not designated” fluoride additives and fluoride additives in public drinking water (fluoridated waters) as federal legend drugs. **But in a CR 12(b)(6) or CR 12(c) motion**

¹¹ 44 FR 42775-78 which publishes the 1979 MOU is attached hereto as R 10-13.

the Court must accept Citizens' facts and not the Cities' facts. (Brief of Appellants at 9-10.)

In support of Citizens' alleged fact that the FDA has determined that fluoridation products are drugs, Citizens presented CP 352-54 which is an official response from the FDA to Congress regarding "the use of fluoride in drinking water." The letter states that such "fluoride, when used in the . . . prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation." (CP 352.) This supports Citizens' alleged fact that FDA has determined that fluoride water additives are drugs subject to FDA regulation, because it is implied that such additives are used in the prevention of dental caries disease. (Brief of Appellants at 19.)

The FDA letter goes on to state that "the Environmental Protection Agency regulates fluoride in the water supply." (CP 352.) This can only refer to the fact that EPA regulates fluoride maximum contaminant levels ("MCLs") for fluoride. MCLs are not fluoride additive standards. (*Infra* at 27-28.) EPA does not regulate fluoride additives. (*Id.*) The FDA letter is dated year 2000. (*Id.*) More than ten years earlier, the EPA had given up the concept of regulating water additives and transferred regulation of additives to the States and utilities, using a third party certification system. (Brief of Appellants at 23-24; *infra* at 29-33; A 16-19; CP 142-45.)

Federal drugs are either prescription or nonprescription. Because FDA has determined that fluoridation products are federal drugs, and determined that they are not OTC drugs, the FDA has determined that they are prescription drugs. If FDA had determined they were OTC anticaries

drug products, FDA would have included them in the OTC Anticaries Drug Products Monograph. (CP 148-91.) FDA has not included fluoride additives in the OTC anticaries drug products monograph (CP 148-91), so the FDA determination remains that fluoridation products are prescription drugs. This Court should give deference to these FDA determinations. (Riegel v. Medtronic, Inc., 552 U.S. 312, 326-27, 128 S.Ct. 999 (2008).) That the FDA has made these determinations should be accepted as an alleged fact for purposes of a CR 12(b)(6) or CR 12(c) motion. (Brief of Appellants at 9-10.)

The FDA determination that fluoridation additives are prescription drugs means that these substances remain prescription drugs when they are added to public drinking waters (fluoridated waters) unless the FDA approves the fluoride and water mixture as a nonprescription drug.¹² But such fluoridated waters are not approved by FDA in the OTC anticaries monograph and not approved by FDA by issuance of a NDA or ANDA. (Brief of Appellants at 15, 34-35; CP 147-91.)

¹² In WAC 246-290-460(2), the state board of health requires fluoride ion concentration in fluoridated water to be 0.8 to 1.3 mg/l which is 0.00008 to 0.00013 percent fluoride ion. 21 CFR 355.60 approves a federal OTC product that is restricted to use by practitioners only where the instruction for children in nonfluoridated areas is to “rinse with 5 milliliters (ml) of 0.02 percent . . . fluoride ion rinse daily, then swallow.” This OTC product has a fluoride ion dose of $(5)(0.02)/100 = 0.001$ gram. One liter of fluoridated water at 1mg/l fluoride ion also contains 1 mg = 0.001 gram of fluoride ion. It is an undisputed fact that fluoridated water and all of the OTC anticaries products are intended to work topically (when the product is in contact with the teeth) even though fluoridated water and these rinses are swallowed. Fluoridated water is not now an OTC approved product. (21 CFR 355.1 et seq.) Swallowed rinses are OTC approved but are restricted to health professionals only (21 CFR 355.60.) So, in Washington State, these products are considered legend drugs. RCW 69.41.010(12) (“‘Legend drugs’ means any drugs which are . . . or are restricted to use by practitioners only.”)

2. **The SDWA regulates contaminants and does not regulate water additives except to control contaminants**

The City Br. at 16 argues that no section of the FFDCA and none of the implementing regulations regulate public drinking water systems. While such systems are not directly mentioned in the FFDCA, it is clear that the FFDCA gives FDA broad authority to regulate foods as designated in 21 U.S.C. 321(f) and drugs as designated in 21 U.S.C. 321(g)(1). (21 U.S.C. 393(b)(2)(A) and (B).) Except for drugs which are controlled substances, the FFDCA and implementing regulations do not generally address drugs by substance name so it is not irregular that fluoride additives and fluoridated water are not specifically mentioned in the drug statutes and regulations.

The SDWA, on the other hand, has a relatively limited scope. The scope was addressed in the Brief of Appellants at 20-21. The SDWA regulates contaminants in water. Under the SDWA, for various regulated water contaminants, the EPA sets a maximum contaminant level (“MCL”) that triggers clean-up enforcement. The SDWA directs the EPA to set a MCL goal (“MCLG”) where some small percent of people will be harmed and then allows the MCL to exceed that goal if cleanup is costly.

It would not be wise to drink water that is at the MCL for a contaminant because some people will be harmed. To be truly safe, a person would want a contaminant in their water to not exceed perhaps one percent or ten percent of the MCL to have a factor of safety. So the MCL is a cleanup standard. It is not an additive standard. The SDWA does not address additives and does not authorize EPA to set regulatory additive standards that

are safe. (Brief of Appellants at 20-21.) So generally the SDWA does not regulate drinking water additives.

A limited exception to this rule is that EPA can authorize additives, like bleach, for the sole purpose of reducing other contaminants in drinking water. Because drugs, like fluoride, are not put in drinking water to reduce other contaminants, EPA is not authorized by the SDWA to regulate and does not regulate such additives. (42 U.S.C. 300f et seq.) There is no provision in the SDWA or EPA's implementing regulations that addresses fluoride additives except 42 U.S.C. 300g-1(b)(11) expressly forbids EPA from adopting a requirement for addition of any substance for preventative health care purposes. (Brief of Appellants at 20, n. 6.)

3. **It is alleged as a fact that WAC 246-290-220(3) that regulates additives generally and WAC 246-290-460 that regulates fluoride additives are not related to the requirements of the SDWA**

EPA has confirmed that the Board of Health rule that regulates public drinking water additives (WAC 246-290-220(3)) and the rule that regulates fluoride additives (WAC 246-290-460) are not related to the requirements of the Federal SDWA, that EPA regulates. To the degree, these rules regulate fluoride additives and fluoride additives in water (fluoridated water), they are regulating drugs. (21 U.S.C. 321(g)(1)(B).)

The board of health is authorized to regulate the health and safety of public drinking water. (RCW 43.20.050(2)(a); City of Port Angeles at 593.) Although the City Br. at 36 states the board is authorized to "promulgate standards for additives" pursuant to RCW 42.30.050(2) [**sic** 43.20.050(2); A 27-29], the Legislature never mentions specific authority to regulate

additives. However, the board of health is not authorized to regulate fluoride additives because they are drugs. The board of pharmacy is the only state board authorized to regulate substances that are drugs. (RCW 18.64.005(7).)

The City Br. at 36 states none of the board of pharmacy rules regulate public drinking water and additives. But a large number of board of pharmacy rules will regulate the Cities' fluoridation when this Court confirms that fluoride additives are drugs.

The City Br. at 28-30 argues that City of Port Angeles at 8-9 found that fluoride is one of the permitted chemical additives allowed by the board of health regulations, and that Appellants claim fluoride is not permitted. It is permitted, but that is the reason for Citizens' constitutional claim. (Brief of Appellants at 39.) It is being permitted by the board of health without requiring evidence of ability to comply with FDA and board of pharmacy regulations. The City of Port Angeles Court did not reach the issue of whether the fluoride additives and fluoridated waters are drugs. (Brief of Appellants at 1.)

The City Br. at 29-30 argues that the Supreme Court has found the Cities' fluoridation systems lawful in City of Port Angeles at 8-9. This is "disingenuous." City of Port Angeles only found the decision to fluoridate to be administrative. (*Id.* at 239 P.3d at 596.)

4. **The 1979 MOU was terminated when EPA gave "Notice" that it was terminating its commitment to FDA to create a federal regulatory drinking water additives program and terminating its commitment to FDA to continue an informal advisory drinking water additives program**

In the Brief of Appellants at 23-24, Citizens argued that the EPA gave notice in 1988 that terminated the 1979 MOU. The City Br. at 18 claims our

argument is “disingenuous and false.” This Court should evaluate the terms of the 1979 Notice with the 1979 MOU (R 10-13) and the 1988 EPA Termination Notice (A16-19) and decide if the Termination Notice was a notice that EPA did not intend to continue to fulfill the agencies’ common understanding of the Terms of Agreement and particularly those terms marked with a D on R 11. While, the notice does not specifically state it is terminating the 1979 MOU, it does terminate the 1979 MOU because EPA announces it will no longer perform the regulatory and advisory functions that it agreed to provide in the 1979 MOU. Compare A 16-19 with R 10-13.

The intent of the 1979 MOU was to avoid “duplicative and inconsistent regulations” controlling public water system additives. (Brief of Appellants at 21.) The 1988 Termination Notice states that EPA was not regulating additives. (Brief of Appellants at 23.) This Notice states EPA was transferring regulation of additives to the States and utilities, using a third party certification system. *Id.*

The Terms of Agreement provided that EPA would establish appropriate federal regulations to control direct additives to public drinking water. (Section III(A)(1) of the 1979 MOU (section marked D on R 11).) Instead, the 1988 Termination Notice provided that no federal agency would have a regulatory program “to control direct additives to drinking water (which encompass any substances purposely added to the water.”) (*See* section III(A)(1) of the 1979 MOU (section marked D on R 11).)

Further, this Notice states that EPA was ending its informal federal advisory program on direct water additives. (A 19, first paragraph.) In Section III(A)(3) of the 1979 MOU (section marked with D on R 11) the

EPA and FDA had agreed that EPA would continue its informal advisory program. But when EPA ended its informal federal advisory program, no federal agency could provide that service. There is no record of the 1979 MOU being modified by mutual consent per Section IV of the MOU. (*See* section marked with E on R 11.) A notice of modification by one party without mutual consent should be considered a notice of termination of the obligations of the agreement and termination of the agreement under Section IV of the MOU.

The City Br. at 18 argues that the 1988 Notice was merely notice of termination of the advisory program. But continuance of this advisory program was a term of agreement of the MOU. (*Supra* at 30-31.)

The City Br. at 18-19 argues that the 1988 EPA Notice affirmed the 1979 MOU because the Notice provided the history of adoption of the MOU. This argument is without merit - its just about presenting the history. The City Br. at 19-21 argues that since 1988, the EPA and FDA have repeatedly affirmed the 1979 MOU. The City Br. at 20 cites to page 3 of 58 FR 378 (1993) which is a response to comments asking FDA to set Maximum Contaminant Level Goals (“MCLGs”) for certain chemicals. (Appendix E to City Br.) The section quoted by the Cities notes such standards (MCLGs and MCLs) for public water systems are set by EPA and not FDA under the SDWA. (*Id.*) This is correct. The quote goes on to state that under the 1979 MOU, FDA is responsible for water in food and food processing and bottled drinking water. (*Id.*) That is a correct statement about the 1979 MOU but this statement does not state that the 1979 MOU is still in effect. The

FFDCA itself gives authority to the FDA for safety of water in food and food processing and bottled drinking water.

Similarly, the City Br. at 20 cites to pages 9-10 of 63 FR 54532 (1998) for a mention of the 1979 MOU. Again, these mentions of the 1979 MOU are historical references and there is no affirmation that the 1979 MOU is still in effect. The document cited goes on to directly interpret the FIFRA and the FFDCA to resolve the subject conflict over regulatory jurisdiction without reliance on the 1979 MOU.

The City Br. at 21 cites to page 31 of 68 FR 58894 (2003) for the proposition that the “FDA again affirmed the continuing application of the 1979 MOU.” This FR document is R 16-17 hereto. It states:

Traditionally, the Environmental Protection Agency (EPA) has exercised a primary role in the regulation of public water systems (*see* 44 FR 42775, July 20, 1979).

(R 17.) Again this does not affirm the continued validity of the 1979 MOU, but just provides a historical note.

But importantly, none of the documents that mention the 1979 MOU, including the MOU itself, suggest that the MOU applies if additives are drugs and if they make the public drinking water a drug under 21 U.S.C. 321(g)(1)(B). The 1979 MOU itself only considers FDA legal authority to regulate food and food additives. (Sections marked A and B on R 10-11.) The word “additives” in the quotes in the City Br. at 18 must be read to not include drug additives. In the 1979 Notice about the 1979 MOU, the EPA states that the agencies agreed that the SDWA implicitly repealed FDA’s jurisdiction “over drinking water as a ‘food’” under the FFDCA. (Section marked F on R 11.) The 1979 MOU should be interpreted to not impact

FDA's jurisdiction over water additives and public drinking water when those substances are drugs under 21 U.S.C. 321(g)(1)(B). (Brief of Appellants at 22-23.)

The City Br. at 21 states that under the SDWA and the 1979 MOU, it could not be more clear that FDA does not regulate public drinking water or additives to public drinking water, much less designate them as federal legend drugs.

But Citizens has alleged as a fact that the FDA has determined that the Cities' fluoridation products are both drugs and prescription drugs and these products remain prescription drugs in fluoridated waters because there is no OTC approval for these waters by the FDA. (*Supra* at 24-26.)

5. **There is no caselaw where a substance or article was not found to be a drug when it met the definition in 21 U.S.C. 321(g)(1)(B)**

There is no caselaw where a substance or article was not found to be a drug by any court when it met the definition in 21 U.S.C. 321(g)(1)(B). If the intended use of the product is to prevent disease, it is a drug. (*United States v. Bowen*, 172 F.3d 682, 686 (9th Cir. 1999).

6. **It is an issue of first impression for this Court as to whether fluoride additives are drugs and prescription drugs**

The City Br. at 10-11 and 39-40 argues that *Kaul* at 625 and *City of Port Angeles* at 6 (n.1)¹³ have held that fluoridated water is not a drug. These cases were addressed in the Brief of Appellants at 1-2 and 38-39. *Kaul* is further addressed *supra* at 9 and 22-24. The City Br. at 34 argues that the mention of not "selling drugs" was a holding. But the Court had already

¹³ The Brief of Appellants used page numbers from P.3d where n. 1 is on page 592.

made its ruling on the case before it considered this issue so the “selling drugs” mention is dicta. (Brief of Appellants at 1.) Furthermore, the Court did not explain why a discussion of the issue would add nothing to its opinion. (Kaul at 625.) Perhaps the City was selling drugs but there was no prohibition on doing so. Legend drugs, which have greater controls, were not defined in this state until 1973. (RCW 69.41.010.)

The City Br. at 18 and 40 cites to Coshow v. City of Escondido, 132 Cal.App.4th 687, 713, 34 Cal.Rptr.3d 19, 34 (2005) for the proposition that FDA’s authority does not extend to public supplies of drinking water. In Coshow, the trial court excluded evidence that the fluoride additive, fluorosilicic acid, was a drug not approved by the FDA to prevent dental caries. (Coshow at 712-13.) The appellant court upheld such exclusion because FDA approval was not relevant to Coshow’s constitutional claims and challenges. (*Id.*) With the evidence that fluorosilicic acid was an unapproved drug excluded, the Coshow Court opines in dicta:

The FDA’s authority over food, drugs and cosmetics, including its regulation of fluoride in various products, does not extend to public supplies of drinking water. . .

...

Nothing in the comprehensive statutory and regulatory scheme of the SDWA requires a risk assessment of contaminants by the FDA or FDA approval of any chemical added to public drinking water.

Coshow at 713. Apparently, the Coshow court was unaware of the fact that the SDWA and the EPA do not regulate water additives but only regulate clean up of contaminants in drinking water. (*Supra* at 11-12 and 27-28.) Apparently, the Coshow court was also unaware of the material presented in the Brief of Appellants at 12-27 including the fact that FDA has made a

determination that fluoridation products are drugs and prescription drugs. In any case, Coshow is not precedent for this Court. The Coshow court at 711, n. 9 finds that even if fluorosilicic acid is a drug, Coshow's constitutional claim would fail.

C. **The Cities' Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are State Drugs, State Prescription Drugs, State Legend Drugs, and State Legend Drugs under Ch. 69.41 RCW**

The Brief of Appellants at 27-32 and 35-38 demonstrates that the Cities' fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are state drugs, state prescription drugs, state legend drugs and state legend drugs under Chapter 69.41 RCW. Under the controlling state statutes (RCW 69.41.010(9)(b), 69.04.009(2), and 18.64.011(11)(b)) they are state drugs because they are federal drugs under 21 U.S.C. 321(g)(1)(B) and the statutory language is effectively the same. (Brief of Appellants at 27-31).

Under the controlling state board of pharmacy regulation for prescription drugs, any drug that is a federal prescription drug is a state prescription drug:

“Prescription drug” means any drug required by state or federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

(WAC 246-879-010(9); A 32; Brief of Appellants at 35-36; *supra* at 4-5.)

Therefore, because the Cities' fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are federal prescription drugs they are also state prescription drugs pursuant to a regulation of the state board of pharmacy. (Brief of Appellants at 35; *supra* at 4-5.)

A federal prescription drug is a state legend drug:

“Legend drugs” means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(RCW 18.64.011(14); Brief of Appellants at 35; *supra* at 4 and 14.)

Therefore, because the Cities’ fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are federal prescription drugs they are also state legend drugs under RCW 18.64.011(14).

Because the Cities’ fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are state prescription drugs pursuant to a regulation of the state board of pharmacy (WAC 246-879-010(9); *supra* at 34) they are legend drugs under RCW 69.41.010(12) which states:

“Legend drugs” means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.

D. RCW 69.41.010(12) Provides That A Drug Is A Legend Drug Under Ch. 69.41 RCW If There Is Any State Law Or State Board Of Pharmacy Regulation That Makes The Drug A State Prescription Drug Or Restricts The Drug To Use By Practitioners Only

RCW 69.41.010(12) provides that a drug is a legend drug under Ch. 69.41 RCW if there is any state law or state board of pharmacy regulation that makes the drug a state prescription drug or restricts the drug to use by practitioners only. The legislature clearly contemplates that there may be more than one statute or regulation that makes drugs state prescription drugs. One regulation or statute may make a certain class of drugs prescription drugs and another regulation or statute may make a different class of drugs prescription drugs. Some drugs may be in both classes, some may be in one class and not in the other, and others may be in neither class. But RCW

69.41.010(12) provides that the only drugs it will exclude from being legend drugs under this statute are drugs that are 1) not made a prescription by any state statute or state regulation and 2) not restricted to use by practioners only.

1. **Considering WAC 246-879-010(9) and WAC 246-883-020(2), all federal prescription drugs are legend drugs under RCW 69.41.010(12)**

Citizens have demonstrated how a federal prescription drug is a legend drug under RCW 69.41.010(12) in reliance on WAC 246-879-010(9). The City Br. at 22 n. 33 claims that a smaller class of drugs are legend drugs under RCW 69.41.010(12) in reliance on WAC 246-883-020(2). But under the legislature’s unambiguous statutory language in RCW 69.41.010(12) a state prescription drug under any state law or state board of pharmacy regulation is a legend drug under RCW 69.41.010(12). Therefore this Court should find that the larger of the two classes controls what is a legend drug under RCW 69.41.010(12). This means that any drug that is a federal prescription drug is also a legend drug under RCW 69.41.010(12). Because the Cities’ fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are federal prescription drugs under Citizens’ alleged facts, this Court should reverse the Order Granting Defendant Cities’ Motion to Dismiss.

E. **It Is An Alleged Fact That The State Board Of Pharmacy Has Determined That Fluoride Water Additives (“Fluorides”) Are State Legend Drugs Under Ch. 69.41 RCW**

The City Br. at 11 and 35-37 argues that whether fluoridated public drinking water should be regulated as a drug is in the primary jurisdiction of the FDA and the state board of pharmacy. Petitioners have presented Citizens’ alleged fact that the FDA has determined that fluoride water

additives are prescription drugs and that these drugs remain prescription drugs when added to public drinking waters as long as there are no over the counter approvals. (*Supra* at 24-26.)

It is also Citizens' alleged fact that the state board of pharmacy has determined that fluoridation substances are legend drugs regulated under chapter 69.41 RCW. (Brief of Appellants at 38.) Bill Osmunson DDS, MPH filed one petition with the state board of health and a second petition with the state board of pharmacy. Together, the responses to these petitions establish that the state board of health understands that the purpose of water fluoridation is to help prevent tooth decay and the state board of pharmacy has determined that fluoridation substances that are intended to prevent tooth decay are legend drugs under Ch. 69.41 RCW.

1. **The state board of health considers it "self evident" that water fluoridation is to prevent tooth decay**

Dr. Osmunson submitted a petition to the state board of health requesting to add an intent statement in two places in WAC 246-290-460, the fluoridation regulation. (CP 124.) The suggested intent statement was "with the intent to prevent dental caries." (*Id.*) The board responded with the statement that it was denying his request because:

The Board considers it self evident that the purpose of water fluoridation is to help prevent tooth decay.

(*Id.*; Brief of Appellants at 19.) Under RCW 34.05.330(1), the board must respond to a petition within 60 days of receipt. (CP 124.) If the petition is denied, the petitioner has 30 days to appeal to the governor. (RCW 34.05.330(3); CP 124.) The final decision was not appealed.

2. **Citizens has alleged as a fact that the state board of pharmacy has made the determination that fluoridation substances in drinking water are legend drugs under Ch. 69.41 RCW**

Citizens has alleged as a fact that the state board of pharmacy has determined fluoridation substances are legend drugs under Ch. 69.41 RCW. (Brief of Appellants at 38; CP 259, Para. 6; CP 276, Para. 6; CP 282, Para. 8; CP 360-64.) In a CR 12(b)(6) or CR 12(c) motion the Court must accept Citizens' facts. (Brief of Appellants at 9-10.)

In support of Citizens' alleged fact that the state board of pharmacy has determined that fluoridation substances are legend drugs under Ch. 69.41 RCW, Citizens presented CP 360-64 which is the formal denial of a petition that Dr. Osmunson submitted to the state board of pharmacy. Dr. Osmunson requested the board to designate fluoridation substances as poisons pursuant to RCW 69.38.010 or, alternatively, to require ingested fluoridation substances for mitigation of human disease be dispensed only as legend drugs. The Board response to his petition denied his request to designate fluoridation substances as poisons and quoted RCW 69.38.020:

All substances regulated under chapters 15.58, 17.21, 69.04, 69.41, and 69.50 RCW; and chapter 69.45 RCW are exempt from the provisions of this chapter [69.38 RCW - Poisons].

(CP 360) The board refused his request to designate such fluoride as a poison because such "Fluoride is a legend drug regulated under chapter 69.41." (*Id.*; Brief of Appellants at 38.) The board response provides pages from the then current 2002 edition of the Red Book, quotes from RCW 69.41.010 and WAC 246-883-020, and comments about fluoridation by water districts (the

Cities are not water districts). (CP 360.) The final decision was not appealed.

This decision provides the determination of the state board of pharmacy that fluoridation substances are legend drugs under Ch. 69.41 RCW. This was presented in great detail to the trial court. (CP 69-70, and CP 84-88.) This Court should give deference to this state board of pharmacy determination. (*See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 326-27, 128 S.Ct. 999 (2008).) That the state board of pharmacy has made these determinations should be accepted as an alleged fact for purposes of a CR 12(b)(6) or CR 12(c) motion. (Brief of Appellants at 9-10.)

Because fluoridation substances meet the definition of a poison, the Board of Pharmacy will likely designate these substances as poisons if this court finds the substances are not drugs. (*See* CP 327 for sodium fluoride.)

F. More Detail On The Legislative History Of RCW 69.41.010(12)

Chapter 69.41 RCW was first adopted in 1973. (*See* adoption notes for RCW 69.41.010 on CP 112.) Chapter 69.41 RCW authorizes criminal and civil enforcement procedures. For example, unauthorized possession of a legend drug with intent to sell is a felony under RCW 69.41.030(2). (CP 113.) Citizens' action for in-place seizure under RCW 69.41.230 and RCW 69.41.060 for a legend drug violation of WAC 246-879-010(9) is a civil

action against the Cities because they qualify as drug manufacturers¹⁴ and distributors.¹⁵

When Ch. 69.41 RCW was adopted in 1973, legend drugs were first defined to be:

“Legend drugs” means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(Former RCW 69.41.010(8) (1973); R 18; Brief of Appellants at 28.) Under this definition a federal prescription drug is a state legend drug. (*Supra* at 35-36 discussing RCW 18.64.011(14).) Then in a criminal case, the Court ruled in 1979 that this definition did not give fair notice of criminal possession and the Court ruled that the statute needed to identify the state regulating agency. (Brief of Appellants at 29-30.) The legislature responded by amending the definition of legend drugs in Ch. 69.41 to the language currently in RCW 69.41.010(12) that identifies the state board of pharmacy as this regulating agency. (R 18; CP 111; Brief of Appellants at 30.)

The legislature also responded by putting former RCW 69.41.010(8) (1973) into the definitions section of Ch. 18.64 RCW where it remains today as RCW 18.64.011(14). (Brief of Appellants at 29-30; R 20-21.) Ch. 18.64 RCW also authorizes criminal and civil enforcement procedures. For example, under RCW 18.64.460(4), it is a misdemeanor for a health care

¹⁴ “Manufacturer” means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer. (WAC 246-879-010(8).)

¹⁵ “Distributor” means a person who distributes. (RCW 69.41.010(8); CP 111.) “Distribute” means to deliver other than by administering or dispensing a legend drug. (RCW 69.41.010(7); CP 111.)

entity to purchase legend drugs at a unlicensed location. Under RCW18.64.310(4) there is a civil action when the department of health, directed by the board of pharmacy, seizes unapproved drugs.

The legislature also responded by adopting RCW 69.41.075 that allows the state board of pharmacy to adopt additional rules to enforce Ch. 69.41 RCW, as necessary. (R 19.) The state board of pharmacy then adopted WAC 246-883-020. (CP 270 as amended.) This regulation creates two alternative classes of prescription drugs that qualify as being legend drugs under RCW 69.41.010(12). (Brief of Appellants at 36-37.)

G. Pursuant To WAC 246-883-020(1), Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Legend Drugs Under Ch. 69.41 RCW

In the Brief of Appellants at 36-38, Citizens demonstrated that the Cities' fluoride additives in public drinking waters (fluoridated waters) are legend drugs under Ch. 69.41 RCW pursuant to WAC 246-883-020(1). WAC 246-883-020(1) is an alternative definition consistent with Citizens' previous analysis that a federal prescription drug is a state legend drug not only under RCW 18.64.011(14) but also under RCW 69.41.010(12) and WAC 246-879-010(9). (Brief of Appellants at 35-36; *supra* at 4 and 35-37.) This definition that a federal prescription drug is a state legend drug is fully adequate for civil cases, such as the instant case, where a manufacturer or distributor of a drug does not comply with the law.

H. Pursuant To WAC 246-883-020(2), Fluoride Additives And Fluoride Additives In Public Drinking Waters (Fluoridated Waters) Are Legend Drugs Under Ch. 69.41 RCW

In the Brief of Appellants at 37-38, Citizens demonstrated that the Cities' fluoride additives and fluoride additives in public drinking waters

(fluoridated waters) are also legend drugs under Ch. 69.41 RCW pursuant to WAC 246-883-020(2). WAC 246-883-020(2) is an alternative definition that is more suitable for criminal cases because it gives a greater “fair notice of conduct forbidden by penal statutes.” (*See* Brief of Appellants at 29-30.)

1. **“Listed in the Red Book” should be liberally construed for civil seizure cases**

WAC 246-883-020(2) includes the ambiguous requirement that a federal prescription drug be “listed” in the Red Book to be a legend drug under this regulation. (Brief of Appellants at 37-38.) Whereas it is sensible to construe the word “listed” narrowly for criminal cases, this same word should be liberally construed for civil seizure cases. The purpose of civil seizure in Ch. 69.41 RCW is to prevent unapproved, illegal and potentially dangerous drugs of manufacturers, wholesalers, and distributors from harming the public. (WAC 246-899-040(1)) These statutes and regulations in a civil case are remedial and seek to provide broad protection to the public and therefore should be liberally construed. (*See* *Go2net, Inc. v. Freeyellow.Com, Inc.*, 158 Wn.2d 247, 253, 143 P.3d 590 (2006); *see also supra* at 7.)

2. **Powdered Sodium Fluoride in quantities above 1/4 pound is a listed product in the Red Book**

The City Br. at 25 argues that bulk powdered sodium fluoride in quantities above 1/4 pound is not adequately “listed” in the Red Book in order to be able to seize the 50 pound bags of sodium fluoride used as a drinking water additive by the City of Forks. There are six manufacturers listed in the Red Book that provide powdered (“POW” means powder - CP 369) sodium fluoride in 1/4 lb and larger packages. (CP 373-74.) The LD50

reported for sodium fluoride is 52 mg/kg. (CP 333.) This means that half of people weighing 50 kg (110 pounds) will die with a one time dose of 2.6 gm (0.005 pounds). This is a very toxic drug.

The sodium fluoride used by the City of Forks has been provided by Solvay Fluorides and is 98.75% pure sodium fluoride. (CP 326.) The official standard for the sodium fluoride chemical is listed in the official United States Pharmacopeia ("USP"). (21 U.S.C. 321(g)(1)(A); CP 99.) "Sodium fluoride" is required to be at least 98% pure. (CP 116-18 and especially CP 117.) Fork's sodium meets this standard of purity. All of the powdered sodium fluorides are listed as USP and so they also meet this 98% pure standard. The "Key to Rx Product Listings" (CP 368) states that the layout for product listings, first lists the Rx product and then supplemental information including manufacturer names, and product quantities in standard billing units. (CP 368.) Here the product in the Red Book is bulk sodium fluoride powder in 1/4 pound and larger packages and so Citizens contend the City of Forks' sodium fluoride is adequately "listed" in the Red Book. This sodium fluoride powder is not found in the OTC section of the Red Book.

The City Br. at 24 argues that their sodium fluoride that will be used with intent to prevent dental caries disease is in 50 pound packages so it should not be considered to be a "listed" product in the Red Book. It should be found sufficient to be considered "listed" that the product is nearly pure sodium fluoride powder in quantities of 1/4 pound or greater. To not find such a federal prescription drug product "listed" would defeat enforcement purposes, and that is not in the public interest. (*See* RCW 69.41.100.)

3. **Fluorosilicic Acid in quantities above 3/4 pound should be considered to be an implied listing in the Red Book**

The City Br. at 46 argues that it is indisputable that fluoridation additives are not listed in the Red Book. Citizens claim the listing of fluorosilicic acid is implied because it is an equivalent source of the active fluoride ions for water fluoridation. When the board of pharmacy determined that fluoridation substances were legend drugs under Ch. 69.41 RCW, it certainly understood that one of these substances was fluorosilicic acid because that is the most common fluoridation product. NSF (now NSF, Int.) is the entity that EPA chose for third party certification of drinking water additives. (A 17.) NSF put out a fact sheet in 2008. (CP 122-23.) In that fact sheet, they explained that three products were being certified as fluoridation substances and the dose of the active ingredient fluoride ions for each product would be the same if about three times the weight of fluorosilicic acid was used per liter of water. (CP 123.) It is reasonable to consider bulk fluorosilicic acid in quantities of 3/4 pounds or more to be listed because it is considered to have the same amount of active ingredient as sodium fluoride and is used for the same purpose.

The LD50 for fluorosilicic acid is 200 mg/kg (CP 342.) So for people 50 kg (110 pounds), half are expected to die with a single dose of 10 gm (0.02 pounds). This is also a very toxic drug. At the hearing the City of Port Angeles held on their State Environmental Policy Act Determination of Non-Significance for water fluoridation, Thomas Locke, MD, MPH, a strong proponent of fluoridation, who was the Health Officer of Jefferson County

at the time and a member of the state board of health, provided written testimony:

Studies are underway by the EPA to determine if fluorosilicates differ from sodium fluoride as a source of fluoride ions. Expert opinion is the fluorosilicates completely dissolve at the levels used in CWF [“Community Water Fluoridation”] systems and provide fluoride ions that are identical to those that would be provided by sodium fluoride systems.

Citizens request that this Court liberally construe the phrase “listed” in the Red Book requirement for a civil proceeding to find that the City of Port Angeles’ fluoridation substances are legend drug under RCW 69.41.010(12) pursuant to WAC 246-883-020(2).

The City Br. at 9 and 23 claims that Citizens’ Complaint admits the fluoridation substances are not in the Red Book citing to CP at 259-60, Para. 6 and 10. The intent of those statements was to note that the exact specifications for the Cities’ products of manufacturer, package size, etc. were not the same for the entries in the Red Books. It did not mean that the products were not adequately “listed.” That was not the intent of the statements cited. Red Book listings should be found to not be a requirement to be a legend drug under RCW 69.41.010(12) and WAC 246-879-010(9) but if this Court finds they are required, it should find the Cities’ fluoridation substances are adequately “listed” in the Red Book for this civil proceeding.

4. **If the fluoridation substances are adequately listed in the Red Book, then these substances remain listed when added to water so the fluoride additives in water (fluoridated waters) remain a “listed” product in the Red Book**

If the fluoridation substances are adequately listed in the Red Book, then these substances remain listed when added to water so the fluoride

additives in water (fluoridated waters) remain a “listed” product in the Red Book.

I. The Cities Misinterpret The Doctrine Of Primary Jurisdiction

While both the FDA and state board of pharmacy have drug regulations that are being violated by the manufacturing and distribution of unapproved fluoride additives and fluoride additives in public drinking waters, there is clearly a hesitancy of these agencies to take enforcement action without support from the judicial system. This is a situation where the state board of health has jurisdiction over the safety of public water systems and the state board of pharmacy has jurisdiction over manufacturing, wholesaling and distribution of drugs. Today, the Cities’ bulk fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are not being subjected to “high drug quality standards” and have not been FDA approved as “safe and therapeutically effective drug products” This is in conflict with the legislative intent in RCW 69.41.100. (*Supra* at 6-7.) By this Court clarifying that these fluoride additives are drugs and prescription drugs, and clarifying that the FDA and board of pharmacy regulates the manufacturing, wholesaling, distribution and use of these drugs, it is likely that the FDA and board of pharmacy will develop an enforcement program and the board of health will aid in compliance with that program.

Because the board of health and board of pharmacy are independent boards, both with authority to regulate different aspects of water fluoridation, it is not possible to resolve this matter by petitioning either board without this Court providing guidance regarding statutory interpretation of agency duties.

The doctrine of primary jurisdiction applies where a claim that is originally cognizable in a court requires the resolution of issues that are within the special competence of an administrative body. Applying the doctrine of primary jurisdiction is discretionary with the court, and when applied its result is to suspend the judicial process pending referral to the administrative body.

(Rabon v. City of Seattle, 107 Wn.App. 734, 741, 34 P.3d 821 (2001).) The application of the doctrine is discretionary but is not appropriate where the issue requires statutory interpretation regarding agency duties. (Northwest Ecosystem Alliance v. Washington Dept. of Ecology, 104 Wn.App. 901, 914-17, 17 P.3d 697 (2001).) It would have been an abuse of discretion by the trial court if he denied the Motion to Amend Complaint on the basis of the doctrine of primary jurisdiction.

J. Relief Requested

1. **Because, under the alleged facts, the Cities' fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are legend drugs under Ch. 69.41 RCW, the trial court's Order Granting Defendant Cities' Motion to Dismiss should be reversed**

Because, under the alleged facts, the Cities' fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are legend drugs under Ch. 69.41 RCW, the trial court's Order Granting Defendant Cities' Motion to Dismiss (CP 7-11) should be reversed.

2. **The trial court's Order Denying Motion to Amend Complaint should be reversed**

Because, under the alleged facts, the Cities' fluoride additives and fluoride additives in public drinking waters (fluoridated waters) are drugs, because the trial court relied on dicta in Kaul and abused discretion, and

because the amendment was not futile, the trial court's Order Denying Motion to Amend Complaint should be reversed.

3. **The trial court's denial of the Cities' request for costs and fees under RCW 4.84.185 and CR 11 should be affirmed**

Because Citizens' Complaint in its entirety is not frivolous or advanced without reasonable cause, and because it is grounded in fact and law, the trial court's denial of the Cities' request for costs and fees under RCW 4.84.185 and CR 11 should be affirmed. Citizens make one claim and request two forms of relief. (*Supra* at 7-8.) Citizens claim is supported by a rational argument on the law and the facts. The trial court did not apply the wrong standard of review. It was not required to put findings in the record but the record supports denial of the Cities' request. The standards of review are provided *supra* at 19-21.

4. **This Court should deny the Cities' request for costs and reasonable attorney fees on appeal under RAP 18.9(a)**

Because Citizens' Appeal is not frivolous, this Court should deny the Cities' request for costs and reasonable attorney fees on appeal under RAP 18.9(a). There are debatable issues in Citizens' appeal upon which reasonable minds might differ and so this case of first impression is not frivolous. (*Supra* at 21-22.)

5. **Citizens should be awarded statutory attorney fees and costs pursuant to 4.84.020 and -.080**

If Citizens prevail on the merits, they should be awarded statutory attorney fees and costs pursuant to 4.84.020 and -.080. (Brief of Appellants at 40.)

V. CONCLUSION

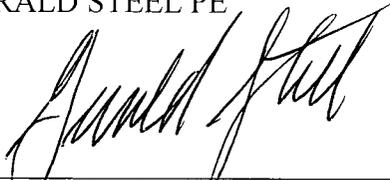
Citizens requests that this Court find under the alleged facts that the Cities' fluoride additives and fluoride additives in public drinking water (fluoridated waters) are federal and state, drugs and prescription drugs, state legend drugs and state legend drugs under the controlling statute RCW 69.41.010(12). Citizens request that the trial court's Order Granting Defendant Cities' Motion to Dismiss and Order Denying Motion to Amend Complaint be reversed. Citizens would like this Court to identify the alleged facts, if any, that must go to trial.

Citizens request that the WACs identified in the Brief of Appellants at 39 in subsection H be invalidated either by section or subsection. This Court should provide guidance regarding statutory interpretation of the duties of the state board of health and state board of pharmacy with respect to water fluoridation. Citizens request that this Court affirm the trial court's denial of the Cities' motion for attorney fees and costs under RCW 4.84.185 and CR 11 and deny the Cities' request for attorney fees and costs under RAP 18.9(a). Citizens request statutory attorney fees and costs under RCW 4.84.020 and -.080 if they prevail on the merits.

Dated this 21st day of February, 2012.

Respectfully submitted,

GERALD STEEL PE


By: _____
Gerald B. Steel, WSBA No. 31084
Attorneys for all Appellants

CERTIFICATE OF SERVICE

I certify that on the 21st day of February, 2012, I caused a true and correct copy of this Certificate and Reply Brief of Appellants/Cross Respondents to be served on the following by first class mail:

Counsel for the Cities of Port Angeles and Forks:

Roger Pearce/P. Steven DiJulio
Foster Pepper PLLC
1111 Third Ave., Ste. 3400
Seattle, WA 98101-3299

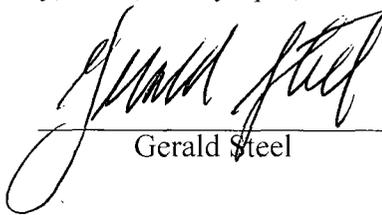
William Bloor
Port Angeles City Attorney
P.O. Box 1150
Port Angeles, WA 98362

William "Rod" Fleck
Forks City Attorney
500 E. Division St.
Forks, WA 98331

and to be personally filed with:

Ronald R. Carpenter, Supreme Court Clerk
Supreme Court State of Washington
P.O. Box 40929
Olympia WA 98504-0929

Dated this 21st day of February, 2012, at Olympia, Washington.



Gerald Steel

APPENDIX INDEX

Page	Item
R 1	21 U.S.C. 535(b)
R 2	21 U.S.C. 379r(a)
R 3	21 U.S.C. 393
R 4	21 U.S.C. 355 (a)
R 5	76 FR 11794-98 (2011) FDA Notice re: Unapproved Drugs
R 10	44 FR 42775-78 (1979) FDA/EPA Notice and 1979 MOU
R 14	2009 Drug Topics Red Book Rx pages for Sodium Fluoride
R16	68 FR 58909-10
R 18	Former RCW 64.41.010(8) (1979)
R 20	Former RCW 18.64.011(6)

Archive

United States Statutes**Title 21. Food and Drugs****Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT****Subchapter V. DRUGS AND DEVICES****Part A. Drugs and Devices***Current through P.L. 111-126***§ 353. Exemptions and Consideration for Certain Drugs, Devices, and Biological Products****(a) Regulations for goods to be processed, labeled, or repacked elsewhere**

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which-

- (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
- (B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only

- (i) upon a written prescription of a practitioner licensed by law to administer such drug, or
- (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or
- (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 352 of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 355 of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the

R I

§ 379r. National Uniformity for Nonprescription Drugs.

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter VII. GENERAL AUTHORITY

Part F. National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics

Current through P.L. 111-290

§ 379r. National Uniformity for Nonprescription Drugs

(a) In general

Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement-

- (1) that relates to the regulation of a drug that is not subject to the requirements of section **353 (b)(1)** or **353 (f)(1)(A)** of this title; and
- (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. **1471** et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption

(1) In general

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that-

- (A) protects an important public interest that would otherwise be unprotected, including the health

R 2

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter X. MISCELLANEOUS

Current through P.L. 111-290

§ 393. Food and Drug Administration

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) Mission

The Administration shall-

- (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
- (2) with respect to such products, protect the public health by ensuring that-
 - (A) foods are safe, wholesome, sanitary, and properly labeled;
 - (B) human and veterinary drugs are safe and effective;
 - (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
 - (D) cosmetics are safe and properly labeled; and
 - (E) public health and safety are protected from electronic product radiation;
- (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
- (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

(c) Interagency collaboration

The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

(d) Commissioner

R3

§ 355. New Drugs.

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter V. DRUGS AND DEVICES

Part A. Drugs and Devices

Current through P.L. 111-290

§ 355. New Drugs

(a) **Necessity of effective approval of application**

[

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug.

(b) **Filing application; contents**

R4

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA-2011-N-0100]

Drugs for Human Use; Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough, or Allergy; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action against unapproved and misbranded oral drug products that are labeled for prescription use and offered for relief of symptoms of cold, cough, or allergy and persons who manufacture or cause the manufacture of such products. These drug products are marketed without approved applications, and many are inappropriately labeled for use in infants and young children. These drug products must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA), or comply with an FDA over-the-counter (OTC) drug final monograph, before marketing.

DATES: This notice is effective March 3, 2011. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section IV.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA-2011-N-0100 and directed to Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002, 301-796-3349, e-mail: sakineh.walther@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:
I. Background
A. Cold, Cough, and Allergy Products Covered by This Notice

This **Federal Register** notice covers certain unapproved and misbranded drug products that are available in oral form and labeled for prescription use.

These products are offered for relief of symptoms relating to cold, cough, or allergy, and include antitussives, expectorants, antihistamines, and nasal decongestants. This notice covers extended-release,¹ tannate, and immediate-release drug products.

B. Regulatory History of Products Covered by This Notice

Many of the drug products covered by this notice contain active ingredients that were introduced into the marketplace without prior review for effectiveness. When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that FDA review and approve "new drugs" for safety, but not effectiveness, before they could legally be sold in interstate commerce.² The FD&C Act made it the sponsor's burden to show FDA that its drug was safe through the submission of an NDA. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)³ to the approved drug to be "covered" by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe. This amendment also required FDA to conduct a retrospective evaluation of effectiveness for all drugs approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study

¹ The term "extended-release" is used in this document to include all timed-release products, including products labeled as "sustained-release," "controlled-release," "delayed-release," or "long-acting." (See 21 CFR 310.502(a)(14).)

² A "new drug" is defined by the FD&C Act as a drug that is not generally recognized, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling (section 201 of the FD&C Act (21 U.S.C. 321(p)).

³ FDA's regulations at (21 CFR 310.6(b)(1)) provide: "An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties."

Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.⁴ Many of the drug products covered by this notice contain the same active ingredients as drug products that were reviewed for effectiveness through the DESI process.

All drugs covered by the DESI review are "new drugs" under the FD&C Act. If FDA's final DESI determination classifies a drug product as ineffective for one or more indications, that drug product and those IRS to it can no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies a drug product as effective for one or more of its labeled indications, the drug, and those IRS to it, can be marketed for such indications, provided each product is the subject of an application approved for safety and effectiveness. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if found effective under DESI; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for these drug products may contain only those indications for which the DESI review found the product effective unless the firm marketing the product has received approval for additional indication(s).

In the early 1970s, FDA granted temporary exemptions from the time limits established for completing certain phases of the DESI program for certain oral prescription drugs offered for relief of cold, cough, allergy, and related symptoms (38 FR 34481, December 14, 1973). The exemptions were granted because of the close relationship between these prescription drugs and OTC drugs, which were subject to the ongoing OTC drug review. (See 21 CFR part 330.) Postponement of final evaluations of these DESI prescription products enabled the Agency to consider the recommendations of the OTC review panel in addition to any evidence submitted by NDA holders and other parties in response to various DESI notices covering relevant products.

II. Safety Concerns With Unapproved New Drugs

Because marketed unapproved new drug products have not been through

⁴ Section 310.6(b)(2) provides that when qualified experts determine that the findings in a DESI notice are applicable to an IRS drug, that IRS drug is affected by the DESI notice.

FDA's approval process, there may be safety risks associated with them. Some unapproved product labeling omits or modifies safety warnings or other information that is important to ensure safe use, such as drug interactions or potential adverse experiences. FDA is particularly concerned about pediatric labeling for these unapproved products. Some of the unapproved products covered by this notice are labeled and marketed for use in children as young as 1 month of age. Without reviewing applications for these products, FDA has no way to assess the scientific support, if any, for the use of these products in pediatric populations.

FDA also has concerns regarding the manufacturing processes for unapproved new drugs and changes in the formulations of these products. When new drugs are marketed without FDA approval, FDA does not have an opportunity, prior to product marketing, to determine whether the manufacturing process for the drugs is adequate to ensure that they are of suitable quality. Additionally, there is no opportunity prior to marketing for FDA to review and approve proprietary names to minimize potential safety issues caused by product name confusion. In fact, FDA has received reports of name confusion associated with unapproved prescription products covered by this notice. Look-alike and sound-alike similarities between product names may contribute to medication errors and adverse events.

Similarly, the new drug approval requirement allows the Agency to evaluate proposed changes to approved product formulations to ensure that such modifications meet FDA standards for safety and effectiveness and to ensure that formulation changes are accompanied, as necessary, by appropriate changes in product proprietary names or labeling, or other measures that may be warranted to minimize confusion and risks to patients. Modifications of product formulations that are not made under FDA's drug approval process thus pose an increased risk of confusing healthcare practitioners and causing harm to consumers, such as underdose or overdose, particularly in pediatric patients.

Finally, FDA has specific safety concerns about the products covered by this notice that are marketed as extended-release products. Many of these products contain amounts of active ingredients that could pose safety risks if the same amount of active ingredient were contained in an immediate-release dosage form. Without prior review of applications for these

products, there is no assurance that the firms that market these products have established appropriate specifications for release of the active ingredients or that the products are properly formulated and manufactured to release their active ingredients to an extent and at a rate that is both safe and effective.

III. Legal Status of Products Identified in This Notice

A. Extended-Release Products

Some of the products covered by this notice are sold as extended-release products. Since 1959, FDA has concluded that all products in extended-release dosage forms are new drugs requiring approved NDAs or ANDAs before being marketed (24 FR 3756, May 9, 1959). Agency review of individual applications for extended-release products is needed to ensure that the finished product releases its active ingredient to an extent and at a rate that is both safe, with a predictable and controlled release of the dose, and effective, sustaining the intended effect over the entire dosing interval. Firms submitting applications are required to establish appropriate release specifications supported by clinical evidence, along with data showing that the finished product as manufactured by the firm releases its active ingredient according to those specifications.

The Agency's determination that all products in timed-release dosage form are new drugs requiring approved applications is codified at 21 CFR 310.502(a)(14). Approval of an NDA under section 505(b) of the FD&C Act (21 U.S.C. 355(b)) or an ANDA under section 505(j) of the FD&C Act is required as a condition for marketing all such products.

The unapproved extended-release drug products subject to this notice are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)) as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁵ A drug that is labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act (21 U.S.C. 353(b)(4)(B)). Thus, if an extended-release drug

⁵ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved extended-release drug products covered by this notice.

covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A) of the FD&C Act, it is misbranded under section 503(b)(4)(B) of the FD&C Act. If an extended-release drug subject to this notice actually meets the definition of "prescription drug" under 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115 (21 CFR 201.100(c)(2) and 201.115)). Because the unapproved prescription extended-release drug products covered by this notice do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1) of the FD&C Act.

B. Tannates

Some of the products covered by this notice contain active ingredients that are in tannate salt form (tannate drugs). FDA has reviewed the publicly available scientific literature on these ingredients, and has determined that unapproved oral drugs labeled for prescription use and offered for relief of symptoms of cold, cough, or allergy that contain the following ingredients are not generally recognized as safe and effective (GRASE): Brompheniramine tannate; carbetapentane tannate; carbinoxamine tannate; chlorpheniramine tannate; dexbrompheniramine tannate; dexchlorpheniramine tannate; dextromethorphan tannate; diphenhydramine tannate; ephedrine tannate; phenylephrine tannate; pseudoephedrine tannate; pyrillamine tannate; and triprolidine tannate. Therefore, products containing these ingredients are new drugs within the meaning of section 201(p) of the FD&C Act, and require approved NDAs or ANDAs before marketing.

The unapproved tannate drug products subject to this notice are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁶ A drug that is

⁶ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously

Continued

labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if a tannate drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A) of the FD&C Act, it is misbranded under section 503(b)(4)(B) of the FD&C Act. If a tannate drug covered by this notice actually meets the definition of "prescription drug," it is misbranded under section 502(f)(1) of the FD&C Act, in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (21 CFR 201.100(c)(2) and 201.115). Because the unapproved prescription tannate drug products covered by this notice do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1) of the FD&C Act.

C. Immediate-Release Products

The remaining unapproved oral products covered by this notice are immediate-release products labeled for prescription use and offered for relief of symptoms associated with cold, cough, or allergy. The immediate-release products fall into the following three categories:

1. Drugs Inappropriately Labeled for Prescription Use

A small number of the immediate-release products covered by this notice conform to the requirements of the final OTC monograph at 21 CFR part 341, "Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use" (the final OTC Cold Cough monograph), except that they are labeled for prescription use only. Section 503(b)(1) of the FD&C Act establishes the definition of a "prescription drug." Drug products that do not meet the definition of a prescription drug but are labeled for prescription use are misbranded under section 503(b)(4)(B) of the FD&C Act. If these drugs conform to the requirements of the final OTC Cold Cough monograph, they are not new drugs and they do not require an approved NDA or ANDA in order to be legally marketed OTC.⁷

does not apply to the unapproved tannate drug products covered by this notice.

⁷ In addition to any other applicable requirements, firms that manufacture OTC drugs must comply with the labeling requirements at 21 CFR 201.66.

2. Drugs Containing Ingredients Included in the Final OTC Cold Cough Monograph But Labeled With Nonconforming Indications or Dosing Regimens

The majority of the immediate-release products covered by this notice are labeled for prescription use and contain ingredients that are included in the final OTC Cold Cough monograph, but have indications, dosing regimens, or both, that are inconsistent with that monograph. FDA has reviewed the indications and dosing regimens (dosing intervals and dosage amounts) in the labeling of over 300 such products, and has reviewed the publicly available scientific literature for studies of these products.⁸ In no case did FDA find literature sufficient to support a determination that one of these products was GRASE for relief of symptoms of cold, cough, or allergy. Therefore, these products are all "new drugs" within the meaning of section 201(p) of the FD&C Act, that require approved NDAs or ANDAs before marketing.

The unapproved immediate-release drug products subject to this notice that contain ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph, are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁹ A drug that is labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if an immediate-release drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A), it is misbranded under section 503(b)(4)(B). If an immediate-release drug covered by this notice does meet the definition of "prescription drug" in 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act.

⁸ The over 300 products reviewed by FDA represent all products in this category that FDA was able to identify.

⁹ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved immediate-release drug products subject to this notice and containing ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph.

in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115). Because the unapproved prescription immediate-release drug products subject to this notice that contain ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph, do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1).

3. Drugs Containing Ingredients Not Included in the Final OTC Cold Cough Monograph

The remaining immediate-release products covered by this notice are labeled for prescription use and contain active ingredients that are not included in the final OTC Cold Cough monograph. FDA has reviewed the publicly available scientific literature on these ingredients, and has determined that the products covered by this notice and offered for relief of symptoms of cold, cough, or allergy that contain the following ingredients are not GRASE: Atropine; carbapentane; cyproheptadine; dyphylline; hyoscyamine; methscopolamine nitrate; phenyltoloxamine; potassium guaiaicosulfonate; promethazine; and scopolamine. Therefore, products covered by this notice containing these ingredients and marketed for relief of symptoms of cold, cough, or allergy are new drugs within the meaning of section 201(p) of the FD&C Act, and require approved NDAs or ANDAs prior to marketing.

The unapproved immediate-release drug products that are subject to this notice and that contain active ingredients not included in the final OTC Cold Cough monograph are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.¹⁰ A drug that is

¹⁰ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved immediate-release drug products covered by this notice that contain active ingredients not included in the final OTC Cold Cough monograph.

labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if an immediate-release drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A), it is misbranded under section 503(b)(4)(B). If a drug covered by this notice meets the definition of "prescription drug" in 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act, in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115). Because the unapproved prescription immediate-release drug products covered by this notice that contain active ingredients not included in the final OTC Cold Cough monograph do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1) of the FD&C Act.

IV. Notice of Enforcement Action

Although not required to do so by the Administrative Procedure Act, the FD&C Act, or any rules issued under its authority, or for any other legal reason, FDA is providing this notice to persons¹¹ who are marketing unapproved and misbranded oral drug products labeled for prescription use and offered for relief of symptoms relating to cold, cough, or allergy that the Agency intends to take enforcement action against such products and those who manufacture them or cause them to be manufactured or shipped in interstate commerce.

Manufacturing or shipping the drug products covered by this notice can result in enforcement action, including seizure, injunction, or other judicial or administrative proceeding. Consistent with policies described in the Agency's guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide" (the Marketed Unapproved Drugs CPG) (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>), the Agency does not expect to issue a warning letter or any other further warning to firms marketing drug products covered by this notice prior to taking enforcement action. The Agency also reminds firms that, as stated in the Marketed Unapproved Drugs CPG, any unapproved drug

marketed without a required approved application is subject to Agency enforcement action at any time. The issuance of this notice does not in any way obligate the Agency to issue similar notices or any notice in the future regarding marketed unapproved drugs.¹²

As described in the Marketed Unapproved Drugs CPG, the Agency may, at its discretion, identify a period of time during which the Agency does not intend to initiate an enforcement action against a currently marketed unapproved drug solely on the ground that it lacks an approved application under section 505 of the FD&C Act. With respect to drug products covered by this notice, the Agency intends to exercise its enforcement discretion for only a limited period of time because there are safety issues with respect to the products covered by this notice and numerous marketed products that have approved applications or comply with the applicable OTC drug final monograph are offered to treat symptoms relating to cold, cough, and allergy. Therefore, the Agency intends to implement this notice as follows.

For the effective date of this notice, see the **DATES** section of this document. FDA intends to take enforcement action against any drug product covered by this notice that is not listed with the Agency in full compliance with section 510 of the FD&C Act (21 U.S.C. 360) before March 2, 2011, and is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after March 3, 2011. FDA also intends to take enforcement action against any drug product covered by this notice that is listed with FDA in full compliance with section 510 of the FD&C Act but is not being commercially used or sold¹³ in the United States on March 2, 2011 and that is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after March 3, 2011.

However, for drug products covered by this notice that are commercially used or sold in the United States, have a National Drug Code (NDC) number listed with FDA, and are in full

¹² The Agency's general approach for dealing with these products in an orderly manner is spelled out in the Marketed Unapproved Drugs CPG. That CPG, however, provides notice that any product that is being marketed illegally, and the persons responsible for causing the illegal marketing of the product, are subject to FDA enforcement action at any time.

¹³ For purposes of this notice, the term "commercially used or sold" means that the product has been used in a business or activity involving retail or wholesale marketing and/or sale.

compliance with section 510 of the FD&C Act before March 2, 2011 ("currently marketed and listed"), the Agency intends to exercise its enforcement discretion as follows. FDA intends to initiate enforcement action against any currently marketed and listed product covered by this notice that is manufactured on or after June 1, 2011 or that is shipped on or after August 30, 2011.¹⁴ Further, FDA intends to take enforcement action against any person who manufactures or ships such products after these dates. Any person who has submitted or submits an application for a drug product covered by this notice but has not received approval must comply with this notice.

The Agency, however, does not intend to exercise its enforcement discretion as outlined previously if the following apply: (1) A manufacturer or distributor of drug products covered by this notice is violating other provisions of the FD&C Act, including, but not limited to, violations related to FDA's current good manufacturing practices, adverse drug event reporting, labeling or misbranding requirements other than those identified in this notice or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of drug products covered by this notice above its usual volume during these periods.

Nothing in this notice, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action, or precludes the Agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the FD&C Act, whether or not related to a drug product covered by this notice. Similarly, a person who is or becomes enjoined from marketing unapproved or misbranded drugs may not resume marketing of such products based on FDA's exercise of enforcement discretion that is set forth in this notice.

Drug manufacturers and distributors should be aware that the Agency is exercising its enforcement discretion as described previously only in regard to

¹⁴ If FDA finds it necessary to take enforcement action against a product covered by this notice, the agency may take action relating to all of the defendant's other violations of the FD&C Act at the same time. For example, if a firm continues to manufacture or market a product covered by this notice after the applicable enforcement date has passed, to preserve limited agency resources, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications at the same time. (See, e.g., *United States v. Sage Pharmaceuticals*, 210 F.3d 475, 479–480 (5th Cir. 2000) (permitting the Agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in "piecemeal fashion").)

¹¹ A "person" includes individuals, partnerships, corporations, and associations (21 U.S.C. 321(e)).

drug products covered by this notice that are marketed under an NDC number listed with the Agency in full compliance with section 510 of the FD&C Act before March 2, 2011. As previously stated, drug products covered by this notice that are currently marketed but not listed with the Agency on the date of this notice must, as of the effective date of this notice, have approved applications prior to their shipment in interstate commerce. Moreover, any person or firm that has submitted or submits an application but has yet to receive approval for such products is still responsible for full compliance with this notice.

V. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Sakineh Walther (*see ADDRESSES*). Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of products covered by this notice. FDA plans to rely on its existing records, including its drug listing records, or other available information when it targets violations for enforcement action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (21 U.S.C. 352 and 355)) and under authority delegated to the Assistant Commissioner for Policy under section 1410.21 of the FDA Staff Manual Guide.

Dated: February 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-4703 Filed 3-2-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a notice in the *Federal Register* of February 2, 2011 (76 FR 7223-7224) announcing an Advisory Committee on Organ Transplantation meeting on March 8, 2011. The type of meeting, time and place have been changed.

Correction

In the *Federal Register* of February 9, 2011, in FR Doc. 2011-2839, on page 7223, 2nd column, under the heading Department of Health and Human Services, Health Resources and Services Administration, Advisory Committee on Organ Transplantation; Notice of Meeting, change the Times and Place to read:

The meeting will be an Audio Conference Call on March 8, 2011, from 12 noon to 4 p.m. EST. To access the conference call, call the USA Toll Free Number 888-469-1090 and enter the Passcode 274119. The conference call leader is Patricia A. Stroup. Participants should call no later than 11:45 a.m. EST in order for logistics to be set up. Participants are asked to register for the conference call by contacting Brittany Carey, HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at (703) 889-9033 or b_carey@team-psa.com. The registration deadline is March 7, 2011. The Department will try to accommodate those wishing to participate in the call.

The next face-to-face ACOT meeting is planned for August 2011. Details regarding an August meeting will be published in a subsequent *Federal Register* notice.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-4755 Filed 3-2-11; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(1) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel: Member Conflict.

Date: March 15, 2011.

Time: 9 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 25, 2011

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-4826 Filed 3-2-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections

Federal facilities. Prior to making a final recommendation to the Administrator, U.S. EPA, the Regional Administrator, Region V, is providing opportunity for public comment on the State of Wisconsin request. Any interested person may comment upon the State request by writing to the U.S. EPA, Region V Office, 230 South Dearborn Street, Chicago, Illinois 60604, Attention: Permit Branch. Such comments will be made available to the public for inspection and copying. All comments or objections received by August 22, 1979, will be considered by U.S. EPA before taking final action on the Wisconsin request for authority to issue permits to Federal facilities.

The State's request, related documents, and all comments received are on file and may be inspected and copied (@ 20 cents/page) at the U.S. EPA, Region V Office, in Chicago.

Copies of this notice are available upon request from the Enforcement Division of U.S. EPA, Region V, by contacting Dorothy A. Price, Public Notice Clerk (312-353-2105), at the above address.

Dated: July 13, 1979.

John McGuire,
Regional Administrator.

FR Doc. 79-22372 Filed 7-19-79; 8:16 am
BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1275-4]

Drinking Water Technical Assistance; Implementation Plan for Control of Direct and Indirect Additives to Drinking Water and Memorandum of Understanding Between the Environmental Protection Agency and the Food and Drug Administration

AGENCY: Environmental Protection
Agency and Food Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have executed a memorandum of understanding (MOU) with regard to the control of direct and indirect additives to and substances in drinking water. The purpose of the MOU is to avoid the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives. The

agreement became effective on June 22, 1979.

ADDRESS: Submit comments to: Victor J. Kimm, Deputy Assistant Administrator for Drinking Water, Environmental Protection Agency (WH-550), Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: David W. Schnare, Ph.D., Office of Drinking Water (WH-550), Environmental Protection Agency, Washington, D.C. 20460, (202) 755-5643; or Gary Dykstra, Enforcement Policy Staff (HFC-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3470.

SUPPLEMENTARY INFORMATION: In the spirit of interagency cooperation and to avoid the possibility of overlapping jurisdiction over additives and other substances in drinking water, FDA and EPA have entered into a memorandum of understanding to avoid duplicative and inconsistent regulation. In brief, the memorandum provides that EPA will have primary responsibility over direct and indirect additives and other substances in drinking water under the Safe Drinking Water Act, the Toxic Substances Control Act, and the Federal Insecticide, Fungicide and Rodenticide Act. FDA will have responsibility for water, and substances in water, used in food and for food processing and for bottled water under the Federal Food, Drug and Cosmetic Act.

Pursuant to the notice published in the Federal Register of October 3, 1974, (39 FR 35697) stating that future memoranda of understanding, and agreements between FDA and others would be published in the Federal Register, the following memorandum of understanding is issued:

Memorandum of Understanding Between the
Environmental Protection Agency and the
Food and Drug Administration

I. Purpose

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

- (1) That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;
- (2) That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;
- (3) That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives

has been the subject of Congressional as well as public concern:

(4) That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

(5) That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

(6) That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, *inter alia*, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

(7) That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, *inter alia*, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

(8) That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, *inter alia*, the adulteration of food by food additives and poisonous and deleterious substances. It is the intent of the parties that:

(1) EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

(2) FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background

(A) *FDA Legal Authority.* "Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA § 201(f)). Under Section 402, *inter alia*, a food may not contain any added, poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 406, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410

A

B

R10

of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and is subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

(B) *EPA Legal Authority.* The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with premanufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, *inter alia*, labeling which specifies how, when, and where a pesticide may be legally used. In

addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement

(A) EPA's responsibilities are as follows:

- (1) To establish appropriate regulations, and to take appropriate measures; under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substances which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.
- (2) To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

(3) To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

(4) To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

(B) FDA's responsibilities are as follows:

(1) To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.

(2) To provide assistance to EPA to facilitate the transition of responsibilities, including:

(a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

(b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

(c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Dated: June 13, 1979.

Douglas M. Costle,
Administrator, Environmental Protection Agency.

Dated: June 22, 1979.

Donald Kennedy,
Administrator, Food and Drug Administration.

Implementation Plan

EPA is concerned that direct and indirect additives may be adding harmful trace chemical contaminants into our Nation's drinking water during treatment, storage and distribution. Direct additives include such chemicals as chlorine, lime, alum, and coagulant aides, which are added at the water treatment plant. Although these chemicals themselves may be harmless, they may contain small amounts of harmful chemicals if their quality is not controlled. Indirect additives include those contaminants which enter drinking water through leaching, from pipes, tanks and other equipment, and their associated paints and coatings. This notice is being published in the Federal Register to solicit public comment on EPA's implementation plan to assess and control direct and indirect additives in drinking water.

Legal Authorities

EPA and the Food and Drug Administration (FDA) signed a Memorandum of Understanding which recognizes that regulatory control over direct and indirect additives in drinking water is placed in EPA. The two agencies agreed that the Safe Drinking Water Act's passage in 1974 implicitly repealed FDA's jurisdiction over drinking water as a "food" under the Federal Food, Drug and Cosmetic Act (FFDCA). Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water. FDA retains jurisdiction over bottled drinking water under Section 410 of the FFDCA and over water (and substances in water) used in food or food processing once it enters the food processing establishment.

In implementing its new responsibilities, EPA may utilize a variety of statutory authorities, as appropriate. The authorities are identified in Appendix A.

Under the Safe Drinking Water Act, EPA has authority to set and enforce maximum contaminant levels and treatment techniques in drinking water for ubiquitous contaminants, to conduct research, to offer technical assistance to States and to protect against imminent

hazards should such situations arise. Under the Toxic Substances Control Act, EPA has authority to review all new chemicals proposed for use related to drinking water, to mandate toxicological testing of existing and new chemicals where there is evidence that such materials may pose an unreasonable risk to health and the environment as well as authority to limit some or all uses of harmful chemicals. Pesticide use is regulated by EPA under the Federal Insecticide, Fungicide and Rodenticide Act. Thus, EPA believes it has adequate authority to deal with additives to drinking water where they may pose a problem.

Past Actions

For more than ten years, the Public Health Service and other organizations which have become part of EPA have provided advisory opinions on the toxicological safety of a variety of additives to drinking water. These historical informal opinions reflect a variety of information provided by manufacturers and reflect changing toxicological concerns over the years. As such, they will require detailed review over the next few years.

General Approach

EPA intends to begin its responsibility over additives to drinking water with a series of analytical studies to determine the composition and significance of the health risks posed by contaminants related to direct and indirect additives to drinking water. A first step in this process will be monitoring studies of the contaminants actually getting into drinking water from generic categories of additives like bulk chemicals, paints and coatings, pipes and equipment.

In the initial six to twelve months, EPA will develop interim administrative procedures, testing protocols, and decision criteria for future toxicological advisories to the States. These will be distributed for public comment once they are developed. All existing opinions will remain in effect until a general review of past opinions can be undertaken using the new procedures. During this development phase, no new opinions will be rendered unless a proposed product can be shown to be virtually identical to a product for which an opinion has already been rendered, on the basis of chemical formulation and production process. New products or new uses of existing products which are proposed for use in drinking water will be subject to the pre-manufacture notice procedures of TSCA.

A more detailed outline of the steps to be taken by EPA follows.

1. *Problem Definition.*—EPA will contract for *in situ* monitoring to determine use patterns and the contribution of trace contaminants to drinking water from:

- a. bulk chemicals.
- b. generic classes of paints and coatings.
- c. pipes and equipment.
- d. coagulant aids.

EPA has already contracted with the National Academy of Sciences to develop a CODEX system of quality control standards for chemicals (direct additives) used in the treatment of drinking water. This effort will take about three years to complete. When finished, the CODEX system, modeled on the existing FDA-inspired CODEX system for chemicals used in processing food, will be largely self-enforcing.

For the indirect additives listed in items b and c above, considerable effort will be expended to identify the trace contaminants involved before the related health risks can be fully evaluated and appropriate recommendations for future use can be assessed.

2. *Review of Past Advisories.*—The same data base derived from *in situ* monitoring will serve as a basis for a structured reassessment of past toxicological advisories which will be conducted by generic classes of use e.g., paints, coagulant aids, etc. Past opinions will be reviewed to insure conformance with and satisfaction of new test protocols and decision criteria that will be developed.

3. *Future Toxicological Advisories.*—Once initial procedures, test protocols and decision criteria are developed, EPA will resume offering toxicological opinions to the States.

General Policy

In assessing additives to drinking water, EPA will be guided by a policy of reducing public health risks to the degree it is feasible to do so. In such determinations, EPA will evaluate the risks and benefits associated with the materials of concern and their substitutes. Economic impacts of agency actions will also be analyzed.

Notwithstanding these procedures, EPA would use its authorities to protect against any direct or indirect additive to drinking water when data and information indicate that the use of any additive may pose an undue risk to public health.

Implementation

To fulfill this program, resources from the Office of Drinking Water, the Office of Research and Development, and the

Office of Toxic Substances will be used. In addition, EPA looks forward to the cooperation of FDA and other Federal regulatory bodies. EPA intends to involve interested industry groups, independent testing groups, State regulatory bodies, interested members of the public, and industry standards groups, in a continued effort to ensure the safety of the Nation's drinking water.

Finally, EPA may recommend specialized legislative authority to regulate additives to drinking water should a situation arise for which legal authorities prove inadequate. } G

Lead responsibility for this new Federal initiative will be in EPA's Office of Drinking Water. Public comments on any or all aspects of the proposed program are requested, and should be directed to the address given in the opening sections of this notice.

Dated: July 13, 1979.

Thomas C. Jorling,

Assistant Administrator for Water and Waste Management.

Appendix A

Safe Drinking Water Act

Section 1412—establishment of national primary drinking water regulations applicable to public water systems to control contaminants in drinking water which may have any adverse effect on human health. This may include maximum contaminant levels, treatment techniques, monitoring requirements, and quality control and testing procedures.

Section 1431—use of emergency powers where a contaminant which is present in water, or is likely to enter a public water system, may present an imminent and substantial endangerment to the health of persons.

Section 1445—establishment of monitoring and reporting requirements applicable to public water systems.

Section 1450—authority to prescribe such regulations as are necessary or appropriate to carry out the Administrator's functions under the Act.

Toxic Substances Control Act

Section 4—testing of chemical substances and mixtures.

Section 5—pre-manufacture notice required for new chemicals or significant new uses.

Section 6—regulation of hazardous chemical substances and mixtures which pose an unreasonable risk of injury to health or the environment, including restrictions on manufacture, processing, distribution, and use.

R12

Section 7—imminent hazards authority including seizure and other relief through civil court action.

Section 8—reporting and retention of information as required by the Administrator, including health and safety studies and notice to the Administrator of substantial risks.

Section 10—research and development. Development of systems for storing, retrieving and disseminating data.

Section 11—inspections and subpoenas and other enforcement and general administration provisions therein.

Federal Insecticide, Fungicide and Rodenticide Act

Section 3—registration of pesticides, including imposition of restrictions and labeling requirements.

Section 6—suspension and cancellation procedures.

[FR Doc. 79-22222 Filed 7-18-79; 8:45 am]

BILLING CODE 6560-01-M

BILLING CODE 4110-03-M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A-1a]

FM Broadcasting Applications Accepted for Filing and Notification of Cut-off Date; Erratum

Released: July 12, 1979.

The FM Application listed below was inadvertently included on the acceptance/cut-off notice, Report No. A-1, BC Mimeo No. 18676, released on June 25, 1979.

BPH-790108AE (New); Cresson, Pennsylvania, Sherlock-Hart Broadcasting, Inc.

Req.: 94.3 MHz, Channel #232A
ERP: 0.600 kW, HAAT: 600 feet.

Accordingly, the application is removed from the acceptance/cutoff list and the August 8, 1979, cutoff date is deleted.

Federal Communications Commission.

William J. Tricarico,
Secretary.

[FR Doc. 79-22422 Filed 7-19-79; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL LABOR RELATIONS AUTHORITY

Official Time of Employees Involved in Negotiating Collective Bargaining Agreements

AGENCY: Federal Labor Relations Authority.

ACTION: Notice Relating to Official Time.

SUMMARY: This notice principally relates to the interpretation of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214) on the questions of whether employees who are on official time under this section while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses, and whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. The notice further invites interested persons to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on such interpretation and to submit written comments concerning these matters.

DATE: Written comments must be submitted by the close of business on August 24, 1979, to be considered.

ADDRESS: Send written comments to the Federal Labor Relations Authority, 1900 E Street, NW., Washington, D.C. 20424.

FOR FURTHER INFORMATION CONTACT: Harold D. Kessler, Deputy Executive Director, 1900 E Street, NW., Washington, D.C. 20424, (202) 632-3920.

SUPPLEMENTARY INFORMATION: The Federal Labor Relations Authority was established by Reorganization Plan No. 2 of 1978, effective January 1, 1979 (43 FR 36037). Since January 11, 1979, the Authority has conducted its operations under the Federal Service Labor-Management Relations Statute (92 Stat. 1191).

Upon receipt of requests and consideration thereof, the Authority has determined, in accordance with 5 CFR 2410.3(a) (1978) and sections 7105 and 7135(b) of the Statute (92 Stat. 1196, 1215), that an interpretation is warranted concerning section 7131 of the Statute (92 Stat. 1214). Interested persons are invited to express their views in writing on this matter, as more fully explained in the Authority's notice set forth below:

To Heads of Agencies, Presidents of Labor Organizations and Other Interested Persons

The Authority has received a request from the American Federation of Government Employees (AFGE) for a statement of policy and guidance concerning whether employees representing an exclusive representative

in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses under the official time provisions of section 7131 of the Federal Service Labor-Management Relations Statute (92 Stat. 1214). Additionally, the National Federation of Federal Employees (NFFE) has requested a major policy statement as to the application of the official time provisions of section 7131(a) of the Statute (92 Stat. 1214) to all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement. AFGE has raised a similar issue in its request.

The Authority hereby determines, in conformity with 5 CFR 2410.3(a) (1978) and section 7135(b) of the Statute (92 Stat. 1215), as well as section 7105 of the Statute (92 Stat. 1196), that an interpretation of the Statute is warranted on the following:

(1) Whether employees who are on official time under section 7131 of the Statute while representing an exclusive representative in the negotiation of a collective bargaining agreement are entitled to payments from agencies for their travel and per diem expenses.

(2) Whether the official time provisions of section 7131(a) of the Statute encompass all negotiations between an exclusive representative and an agency, regardless of whether such negotiations pertain to the negotiation or renegotiation of a basic collective bargaining agreement.

Before issuing an interpretation on the above, the Authority, pursuant to 5 CFR 2410.6 (1978) and section 7135(b) of the Statute (92 Stat. 1215), solicits your views in writing. You are further invited to address the impact, if any, of section 7135(a)(1) of the Statute (92 Stat. 1215) on the above matters and to submit your views as to whether oral argument should be granted. To receive consideration, such views must be submitted to the Authority by the close of business on August 24, 1979.

Issued, Washington, D.C., July 13, 1979.

Federal Labor Relations Authority.

Ronald W. Haughton,

Chairman.

Henry B. Frazier III,

Member.

[FR Doc. 79-22419 Filed 7-19-79; 8:43 am]

BILLING CODE 6325-01-M

R13

RX PRODUCT LISTINGS

PROD./MFR	NDC	AWP	DP	ORC
(25X40ML,LATEX-FREE)				
14.6%, 40 ml 25s	00409-6660-75	19.50	17.00	
(VIAL,FLIPTOP,BULK PKG)				
23.4%, 100 ml 25s	00409-1141-02	51.60	45.25	
250 ml 12s	00409-1130-02	49.10	42.96	
(Hospira) See SYREX				
(Lelco)				
GRA, NA (U.S.P./N.F.)				
1000 gm	82981-1372-02	33.00		
(Mallinckrodt Lab)				
GRA, NA (U.S.P.)				
500 gm	00406-7532-04	17.67		
2500 gm	00406-7532-06	52.62		
(McGuff) See SODIUM CHLORIDE BACTERIOSTATIC				
(Medall) See NORMAL SALINE FLUSH				
(Medisca)				
POW, NA (USP)				
100 gm	38779-0629-05	22.50		
(U.S.P.)				
500 gm	38779-0629-08	31.50		
(USP)				
1000 gm	38779-0629-09	46.50		
2500 gm	38779-0629-01	87.00		
(Parl) See HYPER-SAL				
(PCCA)				
GRA, NA (USP)				
1 gm	51927-1087-00	0.07		
(Sierra) See NORMAL SALINE IV FLUSH SYRINGE				
(Spectrum Pharmacy)				
GRA, NA (U.S.P.)				
500 gm	49452-6690-01	31.33		
2500 gm	49452-6690-02	79.80		
12000 gm	49452-6690-03	248.68		
POW, NA, 500 gm	49452-6700-01	45.33		
2500 gm	49452-6700-02	125.30		
(Vital Signs) See VASCEZE SODIUM CHLORIDE				
(Allscripts)				
REPACK				
SOL, IV (AMP)				
0.9%, 10 ml 25s	54569-1522-00	21.41		EE
(DRx)				
REPACK				
SOL, IJ (10MLX25)				
0.9%, 10 ml 25s	55045-3710-01	50.00		
(Phys Total Care)				
REPACK				
SOL, IJ (AMP,PF)				
0.9%, 3 ml 100s	54868-8028-00	50.04		
IR (PF,LATEX-FREE)				
0.9%, 500 ml 24s	54868-0710-02	91.08		AT
IV (150X5ML)				
0.9%, 5 ml 150s	54868-2827-00	90.58		
(PF)				
0.9%, 10 ml 25s	54868-4484-00	15.95		EE
(20X25ML)				
0.9%, 20 ml 25s	54868-5714-00	53.76		
(NORMAL SALINE,48X50ML)				
0.9%, 50 ml 48s	54868-0710-05	333.12		
(NORMAL SALINE,48X100ML)				
0.9%, 100 ml 48s	54868-0710-03	323.59		EE
(NORMAL SALINE,24X250ML)				
0.9%, 250 ml 24s	54868-0710-06	133.96		
500 ml	54868-0710-01	91.08		EE
1000 ml	54868-0710-00	64.38		EE
(NORMAL SALINE,12X1000ML)				
0.9%, 1000 ml 12s	54868-0710-04	83.75		
(Southwood)				
REPACK				
SOL, IJ (10MLX100)				
0.9%, 10 ml 100s	58016-4995-01	69.34		
SODIUM CHLORIDE BACTERIOSTATIC (Amer Regent)				
sodium chloride				
SOL, IV (M.D.V.)				
0.9%, 30 ml 25s	00517-0848-25	35.94		EE
(Hospira)				
SOL, IV (25X10ML, LS-PLASTIC)				
0.9%, 10 ml 25s	00409-1966-12	21.60	19.00	AP
(25X10ML,LATEX-FREE)				
0.9%, 10 ml 25s	00409-1966-04	16.20	14.25	AP
(25X20ML,LATEX-FREE)				
0.9%, 20 ml 25s	00409-1966-05	21.60	19.00	AP
(FLIPTOP,LS-PLASTIC)				
0.9%, 30 ml 25s	00409-1966-14	38.10	33.25	AP
(VIAL,FLIPTOP PLASTIC)				
0.9%, 30 ml 25s	00409-1966-07	16.50	14.50	AP

PROD./MFR	NDC	AWP	DP	ORC
(McGuff)				
SOL, IV (M.D.V.)				
0.9%, 30 ml	49072-0888-30	1.49		EE
(Phys Total Care)				
REPACK				
SOL, IV (1X750ML,LATEX-FREE)				
0.9%, 750 ml	54868-0116-01	74.31		AP
(Quality Care Prod)				
REPACK				
SOL, IV (1X30ML,LATEX-FREE)				
0.9%, 30 ml	35356-0181-30	6.32		AP
SODIUM CHLORIDE CONCENTRATE (Amer Regent)				
sodium chloride				
SOL, IV (S.D.V.)				
23.4%, 30 ml 25s	00517-2930-25	35.94		
(BULK PACKAGE)				
23.4%, 100 ml 25s	00517-2900-25	93.75		
(APP)				
SOL, IV (S D.V,PF)				
23.4%, 30 ml	63323-0187-30	2.39		
(MAXIVIAL,BULK PACK,PF)				
23.4%, 100 ml	63323-0088-61	9.30		
200 ml	63323-0088-63	17.10		
SODIUM CHLORIDE FLUSH (AMINSO)				
sodium chloride				
SOL, IV (IN 3ML SD SYRINGE,PF)				
0.9%, 2.5 ml 180s	68863-0900-01	570.60		
(IN 12ML SD SYRINGE,PF)				
0.9%, 3 ml 180s	68863-0900-16	556.20		
(IN 6ML SD SYRINGE,PF)				
0.9%, 3 ml 180s	68863-0900-03	576.00		
(IN 12ML SD SYRINGE,PF)				
0.9%, 5 ml 180s	68863-0900-05	649.80		
(IN 6ML SD SYRINGE,PF)				
0.9%, 5 ml 180s	68863-0900-04	586.80		
(IN 12ML SD SYRINGE,PF)				
0.9%, 10 ml 180s	68863-0900-10	729.00		
(Deen Pre-Fid Syr LLC)				
SOL, IV (3ML W/CANNULA)				
0.9%, 2 ml	08450-6011-02	3.70	3.08	
(3ML,PRE-FILLED SYRINGE)				
0.9%, 2 ml	08450-0901-02	2.90	2.42	
(6ML W/CANNULA)				
0.9%, 3 ml	08450-6012-03	3.84	3.20	
(6ML,PRE-FILLED SYRINGE)				
0.9%, 3 ml	08450-0903-03	3.05	2.54	
(12ML W/CANNULA)				
0.9%, 5 ml	08450-6013-05	4.10	3.42	
(12ML,PRE-FILLED SYRINGE)				
0.9%, 5 ml	08450-0905-05	3.30	2.75	
(12ML W/CANNULA)				
0.9%, 10 ml	08450-6014-10	4.50	3.75	
(12ML,PRE-FILLED SYRINGE)				
0.9%, 10 ml	08450-0906-10	3.70	3.08	
SODIUM CHLORIDE/TETRASTARCH				
(Hospira) See VOLUVEN				
SODIUM CHLORIDE/TOBRAMYCIN SULFATE				
(Hospira)				
SOL, IV (PREMIX,24X100ML)				
0.9%-80 mg/100 ml,				
100 ml 24s	00409-3470-23	263.52	230.64	
(PREMIX,LATEX-FREE)				
0.9%-60 mg/50 ml,				
50 ml 24s	00409-3469-13	229.54	200.88	
SODIUM CHROMATE				
(Baker, J.T.) See SODIUM CHROMATE TETRAHYDRATE				
SODIUM CHROMATE CR 51				
(Brecco Diag) See CHROMITOPE SODIUM				
(Mallinckrodt Inc.)				
SOL, IV, 100 uci/ml,				
2.5 ml	80019-N370-25	676.80	564.00	
SODIUM CHROMATE TETRAHYDRATE (Baker, J.T.)				
sodium chromate				
CRY, NA (REAGENT)				
125 gm	10106-3840-04	55.26		
500 gm	10106-3840-01	100.37		
SODIUM CITRATE				
(Baker, J.T.) See SODIUM CITRATE DIHYDRATE				
(Citra) See TRICITRASOL				
(Gallipot) See SODIUM CITRATE DIHYDRATE				
(Humco)				
GRA, NA (U.S.P.)				
454 gm	00395-2691-01	12.59		
(Mallinckrodt Lab) See SODIUM CITRATE DIHYDRATE				
(Medisca) See SODIUM CITRATE DIHYDRATE				

PROD./MFR	NDC	AWP	DP	ORC
(PCCA)				
POW, NA (USP, ANHYDROUS)				
1 gm	51927-1144-00	0.09		
(Spectrum Pharmacy) See SODIUM CITRATE ANHYDROUS				
(Spectrum Pharmacy) See SODIUM CITRATE DIHYDRATE				
SODIUM CITRATE ANHYDROUS (Spectrum Pharmacy)				
sodium citrate				
POW, NA (F.C.C.)				
100 gm	49452-6707-01	35.70		
(U.S.P.)				
100 gm	49452-6711-01	32.73		
(F.C.C.)				
500 gm	49452-6707-02	49.88		
(U.S.P.)				
500 gm	49452-6711-02	48.65		
(F.C.C.)				
2500 gm	49452-6707-03	187.25		
(U.S.P.)				
2500 gm	49452-6711-03	171.33		
SODIUM CITRATE DIHYDRATE (Baker, J.T.)				
sodium citrate				
GRA, NA (U.S.P., F.C.C., A.C.S.)				
500 gm	10106-3649-01	10.79		
2500 gm	10106-3649-05	82.09		
POW, NA (U.S.P., F.C.C.)				
500 gm	10106-3880-01	10.92		
2500 gm	10106-3880-05	91.20		
(Gallipot)				
GRA, NA (U.S.P., N.F.)				
454 gm	51552-0191-08	10.08		
2270 gm	51552-0191-09	29.68		
(Mallinckrodt Lab)				
CRY, NA (U.S.P.)				
500 gm	00408-0734-04	29.53		
2500 gm	00408-0734-08	95.94		
(Medisca)				
POW, NA (U.S.P.)				
100 gm	38779-0543-05	22.50		
500 gm	38779-0543-08	34.50		
(USP)				
2500 gm	38779-0543-01	87.00		
(Spectrum Pharmacy)				
GRA, NA (U.S.P.)				
500 gm	49452-6710-01	39.03		
2500 gm	49452-6710-02	115.33		
12000 gm	49452-6710-03	511.00		
SODIUM COBALTINITRITRIDE (Baker, J.T.)				
POW, NA (A.C.S., REAGENT)				
125 gm	10106-3656-04	69.78		
500 gm	10106-3656-01	209.55		
SODIUM CYANIDE (Baker, J.T.)				
GRA, NA (A.C.S., REAGENT)				
125 gm	10106-3682-04	23.90		
500 gm	10106-3682-01	42.02		
(Mallinckrodt Lab)				
GRA, NA (A.C.S.)				
500 gm	00408-7818-04	29.13		
SODIUM DEHYDROACETATE (PCCA)				
POW, NA, 1 gm	51927-3581-00	0.41		
SODIUM DESOXYCHOLATE				
(PCCA) See DEOXYCHOLIC ACID				
SODIUM DICHROMATE				
(Baker, J.T.) See SODIUM DICHROMATE DIHYDRATE				
SODIUM DICHROMATE DIHYDRATE (Baker, J.T.)				
sodium dichromate				
CRY, NA (A.C.S., REAGENT)				
125 gm	10106-3672-04	77.35		
500 gm				

PROD/MFR	NDC	AWP	DP	OBC
(Baker, J.T.) POW, NA (U.S.P., A.C.S.)				
500 gm.	10106-3689-01	33.10		
2000 gm.	10106-3689-05	284.89		
(Colgate Oral) See LURIDE				
(Colgate Oral) See PHOS-FLUR				
(Colgate Oral) See PREVIDENT				
(Colgate Oral) See PREVIDENT 5000 BOOSTER				
(Colgate Oral) See PREVIDENT 5000 PLUS				
(Colgate Oral) See PREVIDENT DENTAL RINSE				
(Colgate Oral) See THERA-FLUR-N				
(Consolidated Midland)				
CTB, PO, 1 mg, 100s ea.	00223-1773-01	2.50		
1000s ea.	00223-1773-02	15.75		
(Contract Pharmaceutical)				
CTB, PO (SF, GRAPE)				
1.1 mg, 100s ea.	10267-1640-01	4.90		
1000s ea.	10267-1640-04	54.10		
(SF, CHERRY)				
2.2 mg, 100s ea.	10267-1641-01	5.10		
1000s ea.	10267-1641-04	55.10		EE
(Cypress Pharm) See FLUORIDE				
(Cypress Pharm) See NEUTRAL SODIUM FLUORIDE				
(Cypress Pharm) See SF 1.1% GEL				
(Cypress Pharm) See SF 5000 PLUS				
(Dreir Pharmaceutical) See LOZI-FLUR				
(Ethex) See ETHEDENT				
(Fluoritab) See FLUORITAB				
(Gallipot)				
POW, NA, 113.4 gm	51552-0146-04	10.99		
(U.S.P.)				
454 gm.	51552-0146-06	28.91		
(Hi-Tech)				
LIQ, PO (SF, PEACH, DROPS)				
0.5 mg/ml, 50 ml.	50383-0656-50	8.05		
(Humco)				
GEL, DE, 1%, 60 gm.	00802-3923-92	10.93		
(Kirkman Labs) See FLURA-DROPS				
(Kirkman Labs) See FLURA-LOZ				
(Mallinckrodt Lab)				
POW, NA (A.C.S.)				
500 gm.	00406-7636-04	81.55		
(Medisca)				
POW, NA (U.S.P.)				
100 gm.	38779-0094-05	25.50		
500 gm.	38779-0094-08	55.50		
2500 gm.	38779-0094-01	255.00		
(Omnii Intl) See CAVIRINSE				
(Omnii Intl) See CONTROL RX				
(Oral B Lab) See FLUORINSE				
(Pascal Co.) See NEUTRAGARD ADVANCED				
(PCCA)				
POW, NA (USP)				
1 gm.	51927-1038-00	0.48		
(Perry Med)				
CTB, PO (RASPBERRY)				
0.25 mg, 100s ea.	11763-0398-01	2.52		
1000s ea.	11763-0398-04	11.00		
0.5 mg, 100s ea.	11763-0217-01	2.31		
1000s ea.	11763-0217-04	11.00		
(SF, GRAPE)				
1 mg, 1000s ea.	11763-0318-04	11.00		
(SF, RASPBERRY)				
1 mg, 1000s ea.	11763-0317-04	11.00		
(Perry Med) See FLUORABON				
(Pharmascience Labs) See FLUOR-A-DAY				
(Rising) See DENTA 5000 PLUS				
(Rising) See DENTAGEL				
(Spectrum Pharmacy)				
POW, NA (U.S.P.)				
125 gm.	49452-6740-05	42.88		
500 gm.	49452-6740-01	94.50		
2500 gm.	49452-6740-02	416.50		
(Allscripts)				
REPACK:				
CTB, PO, 0.5 mg, 100s ea.	54569-2870-01	5.54		
LIQ, PO, 0.5 mg/ml, 50 ml.	54569-4607-00	7.00		

PROD/MFR	NDC	AWP	DP	OBC
(Dispensing Solutions)				
REPACK:				
CTB, PO (SF, GRAPE)				
1.1 mg, 90s ea.	66336-0680-90	12.98		
TAB, PO, 2.2 mg, 90s ea.	66336-0263-90	8.01		
(DRx)				
REPACK:				
CTB, PO (SF, CHERRY)				
2.2 mg, 100s ea.	55045-3353-00	9.00		EE
(Palmetto)				
REPACK:				
CTB, PO, 2.2 mg, 90s ea.	23490-7679-01	8.19		
100s ea.	23490-7679-00	9.10		
(PD-Rx Pharm)				
REPACK:				
CTB, PO, 1 mg, 120s ea.	55289-0676-98	7.89		
(Phys Total Care)				
REPACK:				
CTB, PO, 1 mg, 120s ea.	54868-5169-00	21.45		
LIQ, PO (DROPS)				
0.125 mg/drp.	54868-1941-00	13.68		
30 ml.	54868-1941-01	12.18		
(SF, PEACH, DROPS)				
0.5 mg/ml, 50 ml.	54868-1941-01	12.18		
(Southwood)				
REPACK:				
CTB, PO, 1 mg, 100s ea.	58016-0978-00	4.84		
LIQ, PO (DROPS)				
0.125 mg/drp.	58016-9077-01	7.70		
30 ml.				
SODIUM FORMALDEHYDE SULFOXYLATE (PCCA)				
sodium formaldehydesulfoxylate				
POW, NA, 1 gm.	51927-3421-00	3.60		
SODIUM FORMALDEHYDE SULFOXYLATE (PCCA) See SODIUM FORMALDEHYDE SULFOXYLATE				
SODIUM FORMATE (Baker, J.T.)				
CRY, NA (A.C.S., REAGENT)				
500 gm.	10106-3700-01	48.26		
2500 gm.	10106-3700-05	226.75		
12000 gm.	10106-3700-07	769.00		
SODIUM GLUCONATE (Amend)				
POW, NA (F.C.C.)				
454 gm.	17317-0901-01	8.40		
2270 gm.	17317-0901-05	33.60		
11350 gm.	17317-0901-08	105.00		
(PCCA)				
POW, NA (USP)				
1 gm.	51927-2377-00	0.10		
(Spectrum Pharmacy)				
POW, NA (U.S.P.)				
500 gm.	49452-6745-01	46.20		
2500 gm.	49452-6745-02	177.63		
12000 gm.	49452-6745-03	539.00		
SODIUM GLYCEROPHOSPHATE (Amend)				
POW, NA (N.F.)				
125 gm.	17317-0510-04	18.20		
454 gm.	17317-0510-01	44.80		
2270 gm.	17317-0510-05	196.00		
SODIUM HEXAMETAPHOSPHATE (Amend)				
sodium polymetaphosphate				
POW, NA (FOOD GRADE)				
454 gm.	17317-1547-01	8.40		
2270 gm.	17317-1547-05	29.40		
11350 gm.	17317-1547-08	87.50		
(Spectrum Pharmacy)				
GRA, NA (F.C.C.)				
500 gm.	49452-6770-01	53.03		
2500 gm.	49452-6770-02	122.85		
SODIUM HYALURONATE (Cypress Pharm)				
hyaluronate sodium				
GEL, TP (1X340GM)				
0.2%, 340 gm.	60258-0026-12	101.12		
SODIUM HYALURONATE 0.1% HYDRATING LOTION (Hi-Tech)				
hyaluronate sodium				
LOT, TP (1X340GM)				
0.1%, 340 gm.	50383-0293-12	78.65		
(1X1000GM)				
0.1%, 1000 gm.	50383-0293-35	140.47		
SODIUM HYALURONATE HYDRATING LOTION (Cypress Pharm)				
hyaluronate sodium				
LOT, TP (1X1000GM, VISCOELASTIC)				
0.1%, 1000 gm.	60258-0025-10	140.47		

PROD/MFR	NDC	AWP	DP	OBC
SODIUM HYDROXIDE (Amend)				
PEL, NA (A.C.S., REAGENT)				
500 gm.	17317-1357-01	11.20		
2500 gm.	17317-1357-05	38.50		
POW, NA (N.F., F.C.C.)				
454 gm.	17317-0511-01	7.00		
2270 gm.	17317-0511-05	23.10		
11350 gm.	17317-0511-08	52.75		
(Baker, J.T.)				
FLA, NA (PURIFIED)				
500 gm.	10106-3734-01	34.25		
2500 gm.	10106-3734-05	88.84		
PEL, NA (F.C.C., N.F.)				
125 gm.	10106-3728-04	25.88		
500 gm.	10106-3728-01	20.85		
(Baker, J.T.) See SODIUM HYDROXIDE 10N				
(Baker, J.T.) See SODIUM HYDROXIDE 25%				
(Baker, J.T.) See SODIUM HYDROXIDE 50%				
(Baker, J.T.) See SODIUM HYDROXIDE 6N				
(Gallipot)				
FLA, NA (TECHNICAL)				
22700 gm.	51552-0624-09	93.80		
PEL, NA (U.S.P., N.F.)				
454 gm.	51552-0080-06	14.42		
(Gallipot) See SODIUM HYDROXIDE 0.1N				
(Gallipot) See SODIUM HYDROXIDE 10%				
(Gallipot) See SODIUM HYDROXIDE 20%				
(Gordon) See SODIUM HYDROXIDE 10%				
(Letco)				
PEL, NA (N.F.)				
500 gm.	62991-2061-01	32.25		
2500 gm.	62991-2061-02	75.00		
(Mallinckrodt Lab)				
PEL, NA (N.F.)				
500 gm.	00406-7680-04	29.26		
(PCCA)				
POW, NA (NF; CAUSTIC SODA)				
1 gm.	51927-1237-00	0.09		
(Spectrum Pharmacy)				
PEL, NA (N.F.)				
500 gm.	49452-6780-01	48.30		
2500 gm.	49452-6780-02	122.33		
12000 gm.	49452-6780-03	427.00		
SODIUM HYDROXIDE 0.1N (Gallipot)				
sodium hydroxide				
SOL, NA, 473 ml.	51552-0556-06	8.40		
SODIUM HYDROXIDE 10% (Gallipot)				
sodium hydroxide				
SOL, NA, 473 ml.	51552-0406-06	14.49		
(Gordon)				
SOL, NA, 60 ml.	10481-3006-01	32.50		
SODIUM HYDROXIDE 10N (Baker, J.T.)				
sodium hydroxide				
SOL, NA (REAGENT, VOLUMETRIC)				
1000 ml.	10106-5674-02	30.39		
4000 ml.	10106-5674-03	52.32		
4000 ml.	10106-5674-06	52.32		
20000 ml.	10106-5674-07	128.75		
SODIUM HYDROXIDE 20% (Gallipot)				
sodium hydroxide				
SOL, NA (W/V)				
473 ml.	51552-0616-06	14.70		
SODIUM HYDROXIDE 25% (Baker, J.T.)				
sodium hydroxide				
SOL, NA (REAGENT)				
1000 ml.	10106-5661-02	39.86		
4000 ml.	10106-5661-03	68.60		
20000 ml.	10106-5661-07	202.34		
SODIUM HYDROXIDE 50% (Baker, J.T.)				
sodium hydroxide				
SOL, NA (REAGENT)				
500 ml.	10106-3727-01	46.66		
4000 ml.	10106-3727-03	103.67		
19000 ml.	10106-3727-07	280.06		
SODIUM HYDROXIDE 6N (Baker, J.T.)				
sodium hydroxide				
SOL, NA (REAGENT, VOLUMETRIC)				
1000 ml.	10106-5672-02	28.63		
4000 ml.	10106-5672-03	44.29		
20000 ml.	10106-5672-07	105.94		
SODIUM HYPOCHLORITE (Baker, J.T.) See SODIUM HYPOCHLORITE 5%				

R15

be evident only when considered in a larger context. *FDA v. Brown & Williamson Tobacco Corp.*, *supra* at 132 (2000).

Consistent with this instruction, FDA has considered other parts of the registration provision in assessing whether the meaning of "food" in section 415(a)(1) is ambiguous. In particular, FDA has considered section 415(b)(1). In defining "facility" for purposes of section 415, Congress expressly exempted "farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer * * *". These exemptions do not make clear whether Congress intended them to cover only food that is ordinarily eaten at some point by consumers primarily for taste, aroma, or nutritive value or whether, for example, a retail food establishment could include retailers of food contact materials, such as retail cookware stores.

The legislative history of section 415 also supports the conclusion that Congress did not speak directly to the meaning of "food" in that Bioterrorism Act provision. Such history is appropriately consulted at *Chevron* step one. *Atherton v. FDIC*, 519 U.S. 213, 228–29 (1997). In particular, the Conference Report to H.R. 3448, which became the Bioterrorism Act, explains what Congress intended by "retail food establishments," which is used to create an exemption from registration:

The Managers intend that, for the purposes of this section, the term "retail food establishments" includes establishments that store, prepare, package, serve, or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer.

H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 133 (2002).

Similarly, the Conference Report notes that the term "non-profit food establishments" includes not-for-profit establishments in which food is prepared for, or served directly to the consumer, such as food banks, soup kitchens, homebound food delivery services, or other similar charitable organizations that provide food or meals for human consumption." (*Id.* at 133–34.) Notably, the examples provided by Congress for both types of exempt food establishments are not those that generally sell or distribute food contact materials. Accordingly, the legislative history of section 415 creates additional ambiguity as to the meaning of "food."

Finally, a review of section 307 of the Bioterrorism Act (the prior notice of food imports provision) and its legislative history confirms that the meaning of the word "food" when used in the Bioterrorism Act, including section 415, is ambiguous. The Bioterrorism Act's registration provision is one piece of several enacted by Congress to enhance the safety of the U.S. food supply. Registration works in concert with prior notice (section 307 of the Bioterrorism Act). This is reflected in section 305(c) of the Bioterrorism Act, which requires that food from an unregistered facility be held at the port when offered for import. Thus, this provision and its legislative history are of particular relevance in determining whether "food" is ambiguous in the registration provision. The legislative history of section 307 of the Bioterrorism Act supports the ambiguity of the term "food" in the Bioterrorism Act. For example, the Conference Report states that the prior notice provision is to be construed not to apply to "packaging materials if, at the time of importation, such materials will not be used for or in contact with food * * *". [See H.R. Conf. Rep. No. 481, 107th Cong., 2d Sess., 136 (2002).] This statement could be read to mean that the term "food" does not include packaging or other materials that contact food.

Having concluded that the meaning of "food" in section 415(a)(1) is ambiguous, FDA has considered how to define the term so as to achieve a "permissible construction" of the registration provision. *Chevron, USA, Inc. v. NRDC, Inc.*, *supra* at 843. In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis. *Bell Atlantic Telephone Co. v. FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc. v. FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002). FDA has determined that it is permissible, for purposes of the registration provision, to exclude food contact materials from the definition of "food."

Excluding food-contact materials (including food packaging) is consistent with the statutory phrase, "food for consumption". section 415(a)(1), in that foods that are "consumed" are generally those intentionally eaten for their taste, aroma, or nutritive value. In addition, excluding food contact materials from "food" in this regulation is consistent with the exemptions in section 415(b)(1), as well as the legislative history of section 415, in that the establishments exempted by statute and the entities used as examples of retail and nonprofit food establishments are

those that sell, distribute, or otherwise provide what is considered food in the conventional sense and, generally speaking, are not purveyors of food contact articles. Finally, restricting "food" to substances other than food-contact materials is consistent with the legislative history of the prior notice provision of the Bioterrorism Act, a provision linked to the registration provision.

As discussed in responses to comments 64 and 65, FDA has also interpreted "food" for purposes of section 415 to exclude pesticides as defined in FIFRA (7 U.S.C. 136(u)). Accordingly, for the reasons discussed in response to this comment and comments 64 and 65, FDA has determined that a reasonable interpretation of "food" for purposes of section 415 is as follows. Section 1.227(b)(4) of this interim final rule has been revised to provide:

Food has the meaning given in section 201(f) of the act, (i) except for purposes of this subpart, it does not include: (A) food contact substances as defined in section 49(h)(6) of the act (21 U.S.C. 348 (h)(6)); or (B) pesticides as defined in 7 U.S.C. 136(u). (ii) Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods.

(Comment 59) One commenter asks FDA to address the foreign facility exemption as it applies to "products that migrate into food from food packaging and other articles that contact food."

(Response) Because the interim final rule excludes food contact substances from the definition of "food," establishments that manufacture/process, pack, or hold food contact materials or components of such materials are not required to register, unless these establishments also manufacture/process, pack, or hold "food" as defined in § 1.227(b)(4).

(Comment 60) A commenter asks whether water collection and distribution facilities are required to register as food facilities if the owner or operator of such facility knows that the water is to be used as a food ingredient. The same commenter asks whether community water systems that supply water to bottled water facilities or to bottled water sources must register.

(Response) FDA has determined that nonbottled drinking water collection and distribution organizations and their

structures should not be included in the definition of "facility" for purposes of registration. Under section 305(a) of the Bioterrorism Act, the term "facility" includes "any factory, warehouse, or establishment." Congress did not specify any definitions for these terms. According to Webster's II New Riverside University Dictionary (1994), the most relevant definition of "establishment" is "a business firm, club, institution, or residence, including its possessions and employees." Where, as here, the statutory language on its face does not clearly establish Congressional intent, it is appropriate also to consider other language in the section, the language and design of the statute as a whole, and the larger context to determine if the term is ambiguous. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000); *Martini v. Federal Nat'l Mortgage Ass'n*, 178 F.3d 1336, 1345 (D.C. Cir. 1999), citing *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281 (1988).

Traditionally, the Environmental Protection Agency (EPA) has exercised a primary role in the regulation of public water systems (see 44 FR 42775, July 20, 1979). Under the Safe Drinking Water Act (42 U.S.C. 300(f) *et seq.*) (SDWA), EPA regulates public water systems, which are water systems that have at least 15 service connections or serve 25 people per day for 60 days of the year. In addition, Title IV of the Bioterrorism Act creates an extensive scheme for protecting from bioterrorism threats community water systems serving over 3,300 persons. Title IV amends the SDWA to require that such community water systems submit to EPA vulnerability assessments of their facilities and emergency response plans to deal with the possibility of a bioterrorist attack. EPA is authorized to provide funds to community water systems to address critical security enhancements and significant public health threats.

FDA believes that the language and design of the Bioterrorism Act, which in Title IV lays out strategies under EPA's authority for protecting the safety and supply of public drinking water, creates ambiguity about whether Congress intended to require drinking water facilities to register with FDA as food facilities. The traditional EPA role in regulating public water systems, as established by federal legislation and implemented by Federal agencies, also creates ambiguity about Congressional intent to include drinking water facilities within the scope of FDA's food registration scheme.

Based on EPA's primacy in regulating public water systems and on the Bioterrorism Act scheme for water

systems in Title IV, FDA concludes that it is reasonable to interpret the term "facility" to exclude nonbottled drinking water collection and distribution establishments, such as community water systems. Therefore, FDA has revised § 1.227(h)(2) to exclude these nonbottled drinking water establishments from the definition of "facility."

Bottled water, on the other hand, has traditionally been regulated by FDA (see 21 U.S.C. 349, 21 CFR parts 129, 165). Moreover, Title IV of the Bioterrorism Act does not address bottled water issues, but only public drinking water systems. Therefore, FDA believes it is reasonable to include establishments that manufacture/process, pack, or hold bottled water in the definition of "facility."

FDA also has primary responsibility for drinking water that is used in the manufacturing/processing of food that is not bottled water. Thus, once drinking water enters a facility where it is used in food manufacturing/processing, the water is regulated by FDA. Because such facilities are food facilities in the first place, they already are required to register with FDA without regard to the water source.

(Comment 61) Several commenters asked whether facilities that produce water coolers, ozone equipment, carbon dioxide, water storage silos, plastic resins, or chlorine must register with FDA.

(Response) Water coolers, ozone equipment, water storage silos, and plastic resins are food-contact substances (section 409(h)(6) of the FD&C Act) and therefore, facilities that manufacture/process, pack, or hold such items are not required to register because these items are not "food" as defined in this regulation. In contrast, carbon dioxide, if used to make carbonated beverages or to aerate food, is a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Similarly, chlorine, if used in bottled water, is also a component of food (section 201(f)(3) of the FD&C Act) that is intended to have a technical effect in the food and therefore, is "food" as defined in this interim final rule. Accordingly, facilities that manufacture/process, pack, or hold carbon dioxide or chlorine that will be used in food products must register. Please see the response to comment 62, which addresses multiuse substances.

(Comment 62) Commenters suggest that foreign facilities that process or refine vegetable oils not intended for direct inclusion in food or animal feed

should be exempt from registration. These commenters argue that where bulk ingredients have both food and non-food uses, the standard for registration should be whether the commodity has been sufficiently refined to be directly added to food.

(Response) This interim final rule requires that any domestic facility that manufactures/processes, packs, or holds "food" must be registered unless the facility satisfies one of the exemptions in § 1.226. Foreign facilities are subject to the same registration requirement except that a manufacturer/process or is not required to be registered if a subsequent facility outside the United States performs further manufacturing/processing of more than a *de minimis* nature. For purposes of the interim final rule, "food" has the definition in section 201(f) of the FD&C Act except that "food contact substances" (section 409(h)(6)) and "pesticides" (7 U.S.C. 136(u)) are excluded from "food." Under section 201(f), "food" means "articles used for food or drink" (section 201(f)(1)) and articles "used for components of any such article" (section 201(f)(3)). The determination of whether a substance is "food" is not a question of intended use. *Nutrilab v. Schweiker*, 713 F.2d. 335, 337 (7th Cir. 1983); *U.S. v. Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959); *U.S. v. 52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940). Courts interpreting the "food" definition in the act have held that articles at both ends of the food continuum are "food" for purposes of the FD&C Act. *United States v. Tiente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995) (live animals for food use are "food" under the FD&C Act); *U.S. v. Technical Egg Products*, *supra*, 171 F.Supp. at 328 (rotten eggs are "food.") Thus, FDA believes that a facility that manufactures/processes, packs, or holds food must be registered (unless subject to one of the exemptions in § 1.226) even if the food is not yet in the form in which it will be used for food. FDA will consider a product as one that will be used for food if the owner, operator, or agent in charge of the facility reasonably believes that the substance is reasonably expected to be directed to a food use. In the case of vegetable oil that is not yet food grade, FDA believes that a facility that manufactures/processes, packs, or holds such oil must be registered (assuming the facility does not qualify for an exemption in § 1.226) if the owner, operator, or agent in charge reasonably believes that oil manufactured/processed, packed, or held at the facility

the same, the board, or official acting for the board, may waive the requirements of this chapter with reference to any purchase or contract.

Passed the House April 25, 1979.
Passed the Senate April 19, 1979.
Approved by the Governor May 7, 1979.
Filed in Office of Secretary of State May 7, 1979.

CHAPTER 138

[Substitute House Bill No. 535]

NONPROFIT CONSOLIDATED SHIPPING ASSOCIATIONS—REGULATION EXEMPTION

AN ACT Relating to motor freight carriers; and adding a new section to chapter 81.80 RCW.

Be it enacted by the Legislature of the State of Washington:

NEW SECTION. Section 1. There is added to chapter 81.80 RCW a new section to read as follows:

(1) Except as provided in subsections (2) and (3) of this section, the provisions of this chapter shall not apply to the operations of a shipper or a group or association of shippers in consolidating or distributing freight for themselves or for their members on a nonprofit basis for the purpose of securing the benefits of carload, truckload, or other volume rates, when the services of a common carrier are used for the transportation of such shipments.

(2) Every shipper or group or association of shippers claiming this exemption shall file with the commission on an annual basis a statement of nonprofit status and such proof of that status as the commission may by rule require.

(3) The commission may examine the books and records of any shipper or group or association of shippers claiming exemption under this section solely for the purpose of investigating violations of this section.

Passed the House March 29, 1979.
Passed the Senate April 25, 1979.
Approved by the Governor May 7, 1979.
Filed in Office of Secretary of State May 7, 1979.

CHAPTER 139

[Substitute House Bill No. 619]

LEGEND DRUGS—PRESCRIPTION—IDENTIFICATION

AN ACT Relating to legend drugs; amending section 1, chapter 186, Laws of 1973 1st ex. sess. and RCW 69.41.010; amending section 3, chapter 186, Laws of 1973 1st ex. sess. as amended by section 1, chapter 69, Laws of 1977 and RCW 69.41.030; adding a new section to chapter 69.41 RCW; and declaring an emergency.

R18

Be it enacted by the Legislature of the State of Washington:

Section 1. Section 1, chapter 186, Laws of 1973 1st ex. sess. and RCW 69.41.010 are each amended to read as follows:

As used in this chapter:

(1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

- (a) A practitioner; or
- (b) The patient or research subject at the direction of the practitioner.

(2) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, whether or not there is an agency relationship.

(3) "Dispense" means to deliver a legend drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(4) "Dispenser" means a practitioner who dispenses.

(5) "Distribute" means to deliver other than by administering or dispensing a legend drug.

(6) "Distributor" means a person who distributes.

(7) "Drug" means:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(c) Substances (other than food, minerals or vitamins) intended to affect the structure or any function of the body of man or animals; and

(d) Substances intended for use as a component of any article specified in clause (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.

(8) "Legend drugs" means any drugs which are required by ~~((any applicable federal or))~~ state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.

(9) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(10) "Practitioner" means:

(a) A physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatrist under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a registered nurse under chapter 18.88 RCW, a licensed practical nurse under chapter 18.78 RCW, an osteopathic

physician's assistant under chapter 18.57A RCW, or a physician's assistant under chapter 18.71A RCW, or a pharmacist under chapter 18.64 RCW.

(b) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a legend drug in the course of professional practice or research in this state.

Sec. 2. Section 3, chapter 186, Laws of 1973 1st ex. sess. as amended by section 1, chapter 69, Laws of 1977 and RCW 69.41.030 are each amended to read as follows:

It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatrist under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a commissioned medical or dental officer in the United States armed forces, marine hospital service, or public health service in the discharge of his official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his official duties, a registered nurse under chapter 18.88 RCW when authorized by the board of nursing, an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the committee of osteopathic examiners, a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners, or a physician licensed to practice medicine and surgery or a physician licensed to practice osteopathy and surgery in any state or province of Canada which shares a common border with the state of Washington: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his license, or to a common or contract carrier or warehouseman, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment.

NEW SECTION. Sec. 3. There is added to chapter 69.41 RCW a new section to read as follows:

The state board of pharmacy may make such rules for the enforcement and administration of this chapter as are deemed necessary or advisable. The board shall identify, by rule-making pursuant to chapter 34.04 RCW, those drugs which may be dispensed only on prescription or are restricted to use by practitioners, only. In so doing the board shall consider the toxicity or other potentiality for harmful effect of the drug, the method of its use, and any collateral safeguards necessary to its use. The board shall classify a drug as a legend drug where these considerations indicate the drug is not safe for use except under the supervision of a practitioner.

In identifying legend drugs the board may incorporate in its rules lists of drugs contained in commercial pharmaceutical publications by making specific reference to each such list and the date and edition of the commercial publication containing it. Any such lists so incorporated shall be available for public inspection at the headquarters of the state board of pharmacy and shall be available on request from the board upon payment of a reasonable fee to be set by the board.

NEW SECTION. Sec. 4. This 1979 act is necessary for the immediate preservation of the public peace, health, and safety, the support of the state government and its existing public institutions, and shall take effect immediately.

Passed the House April 25, 1979.

Passed the Senate April 24, 1979.

Approved by the Governor May 7, 1979.

Filed in Office of Secretary of State May 7, 1979.

CHAPTER 140

[House Bill No. 666]

SCHOOLS—INTERDISTRICT TRANSFER OF STUDENTS—FOOD SERVICE PROGRAM, PRIVATE AGENCY OPERATION

AN ACT Relating to education; and amending section 28A.58.225, chapter 223, Laws of 1969 ex. sess. as last amended by section 111, chapter 275, Laws of 1975 1st ex. sess. and RCW 28A.58.225; amending section 28A.58.136, chapter 223, Laws of 1969 ex. sess. as last amended by section 1, chapter 58, Laws of 1979 and RCW 28A.58.136; creating new sections; and declaring an emergency.

Be it enacted by the Legislature of the State of Washington:

Section 1. Section 28A.58.225, chapter 223, Laws of 1969 ex. sess. as last amended by section 111, chapter 275, Laws of 1975 1st ex. sess. and RCW 28A.58.225 are each amended to read as follows:

A local district may be authorized by the educational service district superintendent to transport and educate its pupils in ~~((another district))~~ other districts for one year, either by payment of a compensation agreed upon by such school districts, or under other terms mutually satisfactory to the districts concerned when this will afford better educational facilities for the pupils and when a saving may be effected in the cost of education: PROVIDED, That notwithstanding any other provision of law, the amount to be paid by the state to the resident school district for apportionment purposes and otherwise payable pursuant to chapter 28A.41 RCW shall not be greater than the regular apportionment for each high school student of the receiving district. Such authorization may be extended for an additional year at the discretion of the educational service district superintendent.

NEW SECTION. Sec. 2. Any school district which utilized the provisions of RCW 28A.58.225 in the 1978-79 school year shall be hereafter

for each period may be used by such board to carry out the purposes of RCW 28A.03.400 through 28A.03.409.

Passed the Senate February 19, 1979.

Passed the House March 8, 1979.

Approved by the Governor March 23, 1979.

Filed in Office of Secretary of State March 23, 1979.

CHAPTER 90

[Substitute Senate Bill No. 2141]

PRACTICE OF PHARMACY—REQUIREMENTS

AN ACT Relating to the practice of pharmacy; amending section 2, chapter 98, Laws of 1935 as last amended by section 40, chapter 34, Laws of 1975-'76 2nd ex. sess. and RCW 18.64.003; amending section 3, chapter 98, Laws of 1935 as last amended by section 2, chapter 18, Laws of 1973 1st ex. sess. and RCW 18.64.005; amending section 19, chapter 38, Laws of 1963 and RCW 18.64.007; amending section 1, chapter 82, Laws of 1969 ex. sess. and RCW 18.64.009; amending section 1, chapter 38, Laws of 1963 and RCW 18.64.011; amending section 1, chapter 121, Laws of 1899 and RCW 18.64.020; amending section 10, chapter 121, Laws of 1899 as last amended by section 1, chapter 201, Laws of 1971 ex. sess. and RCW 18.64.040; amending section 12, chapter 213, Laws of 1909 as last amended by section 2, chapter 201, Laws of 1971 ex. sess. and RCW 18.64.043; amending section 5, chapter 153, Laws of 1949 as last amended by section 3, chapter 201, Laws of 1971 ex. sess. and RCW 18.64.045; amending section 16, chapter 121, Laws of 1899 as last amended by section 4, chapter 201, Laws of 1971 ex. sess. and RCW 18.64.047; amending section 1, chapter 9, Laws of 1972 ex. sess. and RCW 18.64.080; amending section 11, chapter 121, Laws of 1899 as last amended by section 6, chapter 201, Laws of 1971 ex. sess. and RCW 18.64.140; amending section 10, chapter 213, Laws of 1909 as amended by section 10, chapter 38, Laws of 1963 and RCW 18.64.160; amending section 15, chapter 38, Laws of 1963 and RCW 18.64.165; amending section 1, chapter 28, Laws of 1939 and RCW 18.64.245; amending section 13, chapter 121, Laws of 1899 as last amended by section 12, chapter 38, Laws of 1963 and RCW 18.64.250; adding new sections to chapter 18.64 RCW; repealing section 9, chapter 180, Laws of 1923, section 8, chapter 38, Laws of 1963 and RCW 18.64.110; and prescribing penalties.

Be it enacted by the Legislature of the State of Washington:

Section 1. Section 2, chapter 98, Laws of 1935 as last amended by section 40, chapter 34, Laws of 1975-'76 2nd ex. sess. and RCW 18.64.003 are each amended to read as follows:

Members of the board shall meet at such places and times as it shall determine and as often as necessary to discharge the duties imposed upon it. The board shall elect a ~~((chairman))~~ chairperson and a vice chairperson from among its members. Each member shall receive ~~((twenty-five))~~ forty dollars a day for each day actually spent in the performance of his or her official duties and in going to and returning from the place of such performance, together with travel expenses in accordance with RCW 43.03.050 and 43.03.060 as now existing or hereafter amended.

Sec. 2. Section 3, chapter 98, Laws of 1935 as last amended by section 2, chapter 18, Laws of 1973 1st ex. sess. and RCW 18.64.005 are each amended to read as follows:

The board shall:

(1) Regulate the practice of pharmacy~~((;))~~ and administer and enforce all laws placed under its jurisdiction;

(2) Prepare, grade, and administer or determine the nature of, and supervise the grading and administration of, examinations for applicants for pharmacists' licenses~~((: PROVIDED, That this power and duty shall be limited to the four pharmacist members of the board));~~

(3) Examine, inspect, and investigate all applicants for ~~((registration))~~ license as pharmacists or pharmacy interns and ~~((to))~~ grant ~~((certificates of registration))~~ licenses to all applicants whom it shall judge to be properly qualified~~((: PROVIDED, That this power and duty shall be limited to the four pharmacist members of the board));~~

(4) Determine the fees for licenses and examinations;

(5) Employ an executive officer, inspectors, investigators, chemists, and other agents as necessary to assist it for any purpose which it may deem necessary;

~~((5))~~ (6) Investigate violations of the provisions of law or regulations under its jurisdiction, and ~~((to))~~ cause prosecutions to be instituted in the courts ~~((upon advice from the attorney general));~~

~~((6))~~ (7) Make inspections and investigations of ~~((all))~~ pharmacies and other places, including dispensing machines, in which drugs or devices are stored, held, compounded, dispensed ~~((or))~~, sold, or administered to the ultimate consumer, to take and analyze any drugs or devices and to seize and condemn any drugs or devices which are adulterated, misbranded ~~((or))~~, stored, held, dispensed, distributed, administered, or compounded in violation of or contrary to law;

~~((7))~~ (8) ~~((Have the power to))~~ Conduct hearings for the revocation or suspension of licenses, permits ~~((or))~~, registrations, certificates, or any other authority to practice granted by the board, and/or ~~((to))~~ appoint a hearing officer to conduct such hearings;

(9) Issue subpoenas and administer oaths in connection with any investigation, hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the board;

~~((8))~~ (10) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, ~~((narcotics))~~ controlled substances, and the practice of pharmacy, and/or any other laws or rules under its jurisdiction;

~~((9))~~ (11) ~~((Regulate the))~~ Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs~~((, nostrums;))~~ and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare ~~((by promulgating rules and regulations)).~~ Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice ~~((pharmacy))~~ issued by the board;

R20

(12) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter; and

(13) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed in good faith as members of such board. Such immunity shall apply to employees of the board when acting at the direction of the board in the course of disciplinary proceedings.

Sec. 3. Section 19, chapter 38, Laws of 1963 and RCW 18.64.007 are each amended to read as follows:

The board shall employ an executive officer who shall not be a member of the board but who shall be a pharmacist duly licensed in Washington. Said officer shall receive compensation as set by the ~~((governor))~~ appropriate authority, and shall be responsible for:

~~(1) ((Be responsible for)) The ((administration)) administering~~ of all professional and public affairs as directed by the board;

~~(2) ((Report to and proceed with the instructions of the board;~~

~~(3) Carry out all policies and instructions emanating from said board;~~

~~(4) Make, keep and be in charge of all records and record books required to be kept by the board, including a register of all who are required to be licensed)) Appointing, as authorized and delegated by the board, such secretarial, clerical, accounting, and other office assistance as necessary under provisions of chapter 41.06 RCW;~~

~~(3) Reporting to and carrying out all policies and instructions emanating from the board;~~

~~(4) Preparing and maintaining all board records;~~

~~(5) Attending to the correspondence of the board ((and perform all other duties as the board may require)); and~~

~~(6) ((Receive and receipt)) Receiving and receipting~~ for all fees collected.

Sec. 4. Section 1, chapter 82, Laws of 1969 ex. sess. and RCW 18.64.009 are each amended to read as follows:

Employees of the Washington state board of pharmacy, who are ~~((so))~~ designated by the board as enforcement officers, are declared to be peace officers and shall be vested with police powers to enforce chapters 18.64, 18.81, 69.04, ~~((69.32, 69.33,))~~ 69.36 ((and)), 69.40, 69.41, and 69.50 RCW and all other laws administered by the board.

Sec. 5. Section 1, chapter 38, Laws of 1963 and RCW 18.64.011 are each amended to read as follows:

Unless the context clearly requires otherwise, definitions ((as)) of terms shall be as indicated when used in this chapter((:)).

(1) "Person" ((includes individual, partnership, corporation and association)) means an individual, corporation, government, governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(2) "Board" means the Washington state board of pharmacy.

(3) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia((:)) or the official homeopathic pharmacopoeia of the United States~~((or official national formulary.))~~;

(b) ((Articles)) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals((:));

(c) ((Articles)) Substances (other than food) intended to affect the structure or any function of the body of man or other animals((:)); or

(d) ((Articles)) Substances intended for use as a component of any ((articles)) substances specified in ((subclauses)) (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

~~(4) ((Official compendium" shall mean the current revisions of the pharmacopoeia of the United States, homeopathic pharmacopoeia of the United States and national formulary.~~

~~(5) The term)) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (b) to affect the structure or any function of the body of man or other animals.~~

~~((6) The term "federal act" means the federal food, drug and cosmetic act (Title 21, USC 301 et seq., 52 Stat. 1040 et seq.)~~

~~(7) "Narcotic drug," "dangerous drug," "nonproprietary drug" any drug designated as such under or pursuant to the provisions of Title 69 RCW.))~~

(5) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(6) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Prescription" means ((a written or oral)) an order for drugs or devices issued by a ((duly licensed medical)) practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

R21