

COA # 43252-8

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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.

BRIEF OF APPELLANTS

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I. INTRODUCTION

Cities must comply with drinking water laws and regulations when they add chemicals to public drinking water and distribute that water. But when Cities add drugs to drinking water and use drinking water to sell and distribute these drugs to customers, the Cities must also comply with drug laws and regulations. In City of Port Angeles v. Our Water-Our Choice! (“City of Port Angeles”), 170 Wn2d 1, 259 P.3d 598, 594, n. 6 (2010), the majority did not reach the issue of whether fluoride and fluoridated water are drugs because no error was assigned to the trial court’s failure to make these findings. In this brief, appropriate assignments of error are made.

In the instant case, the trial court abused discretion when it refused to allow the complaint to be amended to add a request for a declaration that the Cities’ fluorides and/or fluoridated waters are drugs. (*See* Amended Appellant’s Clerk’s Papers at 204 (“CP 204”).) The trial court claims Kaul v. Chehalis, 45 Wn.2d 616, 277 P.2d 352 (1954) set precedent and that he would be overruling the Kaul Court to find otherwise. (Report of Proceedings at 10 (“RP 10”) (Appendix A, page 8 herein (“A 8”)); A 6.)

The trial court errs. The determination in Kaul is that the City of Chehalis had police power authority to fluoridate. (Kaul at 619 and 625.) After making this determination, the Kaul Court summarily rejected, as irrelevant to its determination, a claim that the City was selling drugs. (*Id.* at 625.) This mention of drugs is dicta. (State ex rel. Lemon v. Langlie, 45 Wn.2d 82, 89, 273 P.2d 464 (1954) (dicta is a court remark not “essential to its determination”).) Dicta does not provide controlling authority. (Matter of Estate of Hansen, 128 Wn.2d 605, 609, 910 P.2d 1281 (1996).)

The trial court's Order Granting Defendant Cities' Motion to Dismiss ("Dismissal Order" (A 1-5)) errs in failing to conclude, based on the alleged facts, that the Cities' fluorides and fluoridated waters are: drugs under federal statute; drugs under State statute; federal prescription drugs; State prescription drugs; State legend drugs; and State legend drugs under Chapter 69.41 RCW.

The Dismissal Order at CP 8-9 (A 2-3) errs in relying on dicta in City of Port Angeles at 592, Note 1, which states:

The FDA exception is essentially meaningless since the Environmental Protection Agency ["EPA"], not the FDA, regulates public drinking water systems.

The trial court uses this dicta, first, to conclude erroneously "that the FDA does not regulate public drinking water or additives to public drinking water" and, second, to conclude erroneously that the Cities' fluorides and fluoridated waters are not federal prescription drugs. (A 2-3.) City of Port Angeles at 596 determined that certain initiatives are beyond the initiative power because they are "administrative." Said Note 1 is unrelated to that determination and, thus, is dicta. (*Supra.*) If the Supreme Court finds this material in Kaul and City of Port Angeles is not dicta, then the Court is requested to overrule, clarify, or distinguish these cases to the degree they hold or imply that the Cities' fluorides and fluoridated waters are not drugs.

This Court should correct the above errors of law and reverse the trial court's orders (A 1-5 and A 6-7). This Court should also find that WAC 246-290-220(3) as it applies to drugs, and WAC 246-290-460(2), and - (3)(b)(iv)(A) setting fluoride levels violate U.S. Const. Art. VI, cl. 2.

II. ASSIGNMENTS OF ERROR

No. 1. Error in failure to find in A 1-7 that, given the alleged facts, or as a matter of law, the Cities' fluoride substances used to make fluoridated waters and the Cities' fluoridated waters (added fluorides distributed in water) are:

- (a) drugs under federal statutes adopted by Congress;
- (b) drugs under State statutes adopted by the Legislature;
- (c) federal prescription drugs;
- (d) State prescription drugs;
- (e) State legend drugs; and
- (f) State legend drugs under Chapter 69.41 RCW.

No. 2. Error in failure to find in A 1-7 that the States' water fluoridation regulations [WAC 246-290-220(3) requiring ANSI/NSF Standard 60 fluoride and WAC 246-290-460 requiring a fluoride concentration range] are unconstitutional (U.S. Const. Art. VI, cl. 2) under the trial court orders because they require what is not lawful under federal law.

No. 3. Abuse of discretion re: Order Denying Motion to Amend (A 6-7):

- (a) erroneously finding the amendment is futile (A 6; RP 10); and
- (b) erroneously relying on dicta in Kaul (RP 10).

No. 4. Errors of law in dismissing the Complaint and issuing the Dismissal Order (A 1-5) under CR 12(b)(6) and CR 12(c), including:

- (a) errors of omission addressed in Assignments No. 1(a) to (f) above (A 1-5);

(b) errors in A 1-5 in failing to correctly state the jurisdiction of the: EPA; FDA; State Board of Health; State Department of Health (A 2, ¶ 4); State Board of Pharmacy;

(c) error in finding there is valid notice that FDA doesn't regulate public drinking water and additives under "drug" authority (A 2, ¶ 5);

(d) error in relying on dicta in City of Port Angeles for confirmation that FDA doesn't regulate public drinking water and additives under "drug" authority (A 2, ¶ 5);

(e) error in limiting analysis of State "legend drug" status to consideration of WAC 246-883-020(2) (A 2-3, ¶ 6-8);

(f) error in concluding FDA does not regulate public drinking water and additives today such that these cannot be federal legend drugs (A 2-3 ¶ 7 and 9);

(g) error in finding that listing in the Red Book is a requirement to be classified as a "legend drug" in Chapter 69.41 RCW (A 2-3, ¶ 6 and 8);

(h) error in finding that the Cities' bulk fluorides (alone and as distributed in water as fluoridated waters) are not adequately listed in the Red Book (A 2-3, ¶ 8); and

(i) error in finding no set of facts can be proven to show public drinking waters and/or the Cities' fluoride additives are legend drugs (A 3, ¶ 9).

III. MAJOR ISSUES BEFORE THE COURT

No. 1. Under any facts that could possibly be established, can the Cities' fluoridated waters, and/or bulk fluoride products, be drugs pursuant to RCW

18.64.011(11), RCW 69.04.009, RCW 69.41.010(9) and/or 21 U.S.C. § 321(g)(1)? (Assignments of Error Nos. (“Errors”) 1 to 4.)

No. 2. Did the trial court abuse its discretion and should it be reversed, when it denied Citizens’ Motion to Amend Complaint when the amendment proposed adding a declaratory judgment requesting that the trial court declare that the Cities’ fluoridated waters, and/or bulk fluoride products, are drugs? (Errors 1 to 3.)

No. 3. Should this Court overrule, clarify, or distinguish Kaul¹ and City of Port Angeles² to the degree that these cases hold or imply that municipal fluoridated waters, and their bulk fluoride products, cannot be or are not drugs? (Errors 1 to 4.)

No. 4. Under any facts that could possibly be established, can the Cities’ bulk fluoride products, and/or fluoridated waters, be prescription drugs under federal law and regulation and therefore legend drugs under RCW 18.64.011(14)? (Errors 1 to 4.)

No. 5. Under any facts that could possibly be established, can the Cities’ bulk fluoride products, and/or fluoridated waters, be legend drugs under Chapter 69.41 RCW such that the Order Granting Defendant Cities’ Motion to Dismiss should be reversed? (Errors 1 to 4.)

a) If the Cities’ bulk fluoride products, and/or fluoridated waters, can be prescription drugs under federal law and regulation, and legend drugs

¹ Kaul v. City of Chehalis (“Kaul”), 45 Wn.2d 616, 277 P.2d 352 (1954).

² City of Port Angeles v. Our Water-Our Choice! (“City of Port Angeles”), 170 Wn.2d 1, 239 P.3d 589 (2010).

under RCW 18.64.011(14), can they be legend drugs under RCW 69.41.010(12) independent of WAC 246-883-020? (Errors 1 to 4.)

b) Can the Cities' bulk fluoride products, and/or fluoridated waters, be legend drugs under WAC 246-883-020(1)? (Errors 1 to 4.)

c) Can the Cities' bulk fluoride products and/or fluoridated waters be legend drugs under WAC 246-883-020(2)? (Errors 1 to 4.)

IV. STATEMENT OF THE CASE

The Petitioners below (Appellants herein) are Protect the Peninsula's Future, Clallam County Citizens for Safe Drinking Water, and Eloise Kailin (collectively "Citizens"). (CP 257-58.) The Respondents are City of Port Angeles and City of Forks (collectively "Cities"). (CP 257.) The Cities each operate a public drinking water utility that is not a water district. (A 1.) The Cities each provide a fluoridation program for their public drinking water utility. (A 1.) The City of Forks' fluoride source is bulk sodium fluoride which is over 98% pure. (CP 260, ¶ V.7, CP 405, ¶ 2.11; CP 379-80.) The City of Port Angeles fluoride source is bulk fluorosilicic acid (H₂SiF₆) which includes some hydrogen fluoride (HF). (CP 260, ¶ V.9, CP 405, ¶ 2.13; CP 376-78.) The Complaint includes certain pages from the 2009 Drug Topics Red Book which are reproduced by the Cities in CP 34-44. (CP 365-74.)

Based on sworn and certified facts and documents in the record, Citizens further allege the following major facts:

- that the Cities manufacture, offer for sale, and distribute fluoridated waters (fluorides added to waters) to their municipal customers; (CP 258-59, ¶ V.1.)

● that the Cities' fluorides and fluoridated waters are intended for use in the prevention of disease, specifically dental caries [tooth decay]; (CP 259, ¶ V.4.)

● that the Cities' store bulk fluorides for use in their fluoridation facilities and offer the fluorides for sale in fluoridated waters; (CP 258-59, ¶ V.1 and V.3.)

● that the Cities require and do not have an approved NDA (New Drug Application) or ANDA (Abbreviated NDA) from the FDA for their fluoridated waters, and the sodium fluoride and fluorosilicic acid, distributed with their fluoridated waters, require and do not have an approved NDA or ANDA. (CP 260, ¶ V.11.)

● that the City of Forks first began manufacturing fluoridated water with sodium fluoride in 2001 (CP 74), and that the City of Port Angeles first began manufacturing fluoridated water in 2006 (CP 75).

Citizens prepared a certified complaint with a sworn affidavit (CP 275-78), certified First Declaration (CP 279-388) and civil warrants for search and seizure as authorized by RCW 69.41.230 (CP 267) and RCW 69.41.060 (CP 268). On April 20, 2011 Citizens applied ex parte to the Honorable S. Brook Taylor, Judge of the Clallam superior court, for search and seizure warrants based on these documents. (CP 263, Note 1.) Judge Taylor entered an order which found "the issues raised need to be publicly litigated . . . before any searches or seizures are justified." (CP 265.)

On April 28, 2011, Citizens filed and served its Certified Complaint for Search and Seizure Warrants (CP 257-388) including the First Declaration

of Eloise Kailin (CP 279-388), [Proposed] Search and Seizure Warrants (CP 271-74), the Affidavit of Eloise Kailin in Support of Search and Seizure Warrants (CP 275-78), and the Second Declaration of Eloise Kailin (CP 234-56). Clallam County superior court Judges S. Brook Taylor and George Wood recused themselves and an affidavit was filed against the Honorable Judge Ken Williams. The parties agreed to hear the case in Jefferson County before visiting Judge, the Honorable Craddock Verser.

The Cities filed and served Defendant Cities' Motion to Dismiss (CP 205-33) which included a request for attorneys' fees under both RCW 4.84.185 and CR 11. (CP 216-19.) Citizens filed and served Petitioners' Motion to Amend Complaint to add a declaratory judgment requesting the court to "declare that the Cities' fluoridated waters and/or the bulk fluoride products used to make these waters are drugs." (CP 200-04.) On June 17, 2011, the trial court first heard and denied Citizens' Motion to Amend. (RP 2-10; A 6-7.) The trial court then heard and granted the Cities' Motion to Dismiss but denied the Cities' request for sanctions stating:

I will not grant the sanctions because I believe that Petitioners are acting in good faith and arguing for a good faith change to the law . . .

(RP 40; A 1-5.)

Citizens timely-filed and served a Notice of Appeal to Supreme Court on July 5, 2011. (CP 5-13.) The Cities timely-filed and served a Notice of Cross-Appeal on July 18, 2011. (CP 394-401.) Citizens timely-filed and served its Statement of Grounds for Direct Review on July 20, 2011 along with the Third Declaration of Eloise Kailin. The Cities did not respond.

V. ARGUMENT

A. Standard Of Review

1. Standard of review for a CR 12(b)(6) motion

Defendants brought their Motion to Dismiss under CR 12(b)(6) (“failure to state a claim upon which relief can be granted”) and CR 12(c) (“motion for judgment on the pleadings”). (CP 209.) Whether the Motion to Dismiss should be granted is a question of law that this Court reviews de novo. (San Juan County v. No New Gas Tax, 160 Wn.2d 141, 164, 157 P.3d 831 (2007).) Such motions should be granted “sparingly and with care,” and only in the unusual case in which the plaintiff’s allegations show on the face of the complaint an insuperable bar to relief. (*Id.*) Under CR 12(b)(6) a petitioner states a claim upon which relief can be granted if it is *possible* that facts could be established to support the allegations in the complaint. (McCurry v. Chevy Chase Bank, FSB, 169 Wn.2d 96, 101, 233 P.3d 861 (2010).)

2. Standard of review for a CR 12(c) motion

Similarly, a dismissal under CR 12(c) is appropriate only if it appears beyond doubt that the plaintiff can prove no set of facts, consistent with the complaint, which would entitle the plaintiff to relief. (M.H. v. Corporation of Catholic Archbishop of Seattle, 252 P.3d 914, 917 (2011).) In undertaking such an analysis, the plaintiff’s allegations are presumed to be true and a court may consider hypothetical facts not included in the record. (*Id.*) The facts alleged in the complaint, as well as hypothetical facts, are to be taken in the light most favorable to the nonmoving party. (*Id.*) A motion to dismiss under CR 12(c) should be granted sparingly and with care, and only in the unusual

case in which plaintiff includes allegations that show on the face of the complaint that there is some insuperable bar to relief. (*Id.* at 918.) Appellant review of a CR 12(c) dismissal is de novo. (*Id.* at 917.)

3. **Standard of review for Order Denying Motion to Amend Complaint**

CR 15(a) allows parties to amend their pleading by leave of court and directs that leave shall be freely given when justice so requires. A motion for leave to amend the complaint is addressed to the sound discretion of the trial court. (Tagliani v. Colwell, 10 Wn.App. 227, 233, 517 P.2d 207 (1973).) When reviewing the trial court's decision to grant or deny leave to amend, the Court applies a manifest abuse of discretion test. (Wilson v. Horsley, 137 Wn.2d 500, 505, 974 P.2d 316 (1999).) The trial court's decision will not be disturbed on review except on a clear showing of abuse of discretion, that is, discretion manifestly unreasonable, or exercised on untenable grounds, or for untenable reasons. (*Id.*) The touchstone for the denial of a motion to amend is the prejudice such an amendment would cause to the nonmoving party. (*Id.*) CR 15(a) was designed to facilitate the amendment of pleadings except where prejudice to the opposing party would result. (Caruso v. Local Union No. 690 of Intern. Broth. of Teamsters, Chauffeurs, Warehousemen and Helpers of America, 100 Wn.2d 343, 349, 670 P.2d 240 (1983).)

4. **Standard of review for argument that WAC 246-290-220(3), requiring ANSI/NSF Standard 60 fluoride, and WAC 246-290-460, requiring a fluoride concentration range, violate U.S. Const. Art. VI, cl. 2 (Supremacy Clause)**

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution.³ Although there is a presumption that the "historic police powers of the States" will not be preempted by federal law, that presumption can be overcome if Congress intends that the federal law preempt state law. (All-Pure Chemical Co. v. White, 127 Wn.2d 1, 5, 896 P.2d 697 (1995).) Federal law preempts state law when Congress intends to occupy a given field, when state law directly conflicts with federal law, or when state law would hinder accomplishment of the full purposes and objectives of the federal law. (*Id.* at 6.) Preemption may be either express or implied, and is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose. (*Id.*)

Where state law and federal law directly conflict, state law must give way. (Pliva, Inc. v. Mensing, ___ U.S. ___, 131 S.Ct. 2567, 2577, ___ L.Ed.2d ___ (2011).) State and federal law conflict arises where it is impossible for a third party to comply with both state and federal requirements. (Fidelity Federal Savings & Loan Association v. De la Cuesta, 458 U.S. 141, 153, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982).) Federal regulations have the same preemptive power as federal statutes. (McCurry v. Chevy Chase Bank, FSB, 169 Wn.2d 96, 100, 233 P.3d 861 (2010).) Questions of law, including preemption, are reviewed de novo. (*Id.*)

³ "This Constitution, and the laws of the United States which shall be made in pursuance thereof; ... shall be the supreme law of the land; and the judges in every state shall be bound thereby, any thing in the Constitution or laws of any state to the contrary notwithstanding." (U.S. Const. art. VI, cl. 2.)

B. The Cities' Fluoride Additives And Fluoridated Waters Are Drugs

1. Review of Federal drug laws and regulations

a. The 1906 and 1938 Acts

Drug regulation in the United States began with the Colonies and States adopting isolated laws as early as 1736. (Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 703-04 (D.C. Cir. 2007).) As early as 1848, the United States began limited drug regulation. (*Id.* at 704.) Congress adopted more comprehensive drug statutes in the Food and Drugs Act of 1906, which prohibited the manufacture of any drug that was “adulterated or misbranded.” (*Id.* at 705.) This Act defined “drug” as:

all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals;

and defined “food” as including “articles used for food [and] drink.” (Food and Drugs Act of 1906, 34 Stat. 768 (1906).)

Initially, this Act did not regulate false claims of the curative power of a drug but this was changed by Congress in 1912. (Samuels v. United States, 232 F. 536, 545 (8th Cir. 1916).) The 1906 Act, as amended, did not require government approval before a drug was introduced into the market. (United States v. Hiland, 909 F.2d 1114, 1125 (8th Cir. 1990).) This changed with the adoption by Congress of the Federal Food, Drug, and Cosmetic Act (“FFDCA”) of 1938 which required a FDA approved new drug application (“NDA”) to demonstrate a drug was safe before entering the market.

(Samuels at 545.) No new approvals were required for drugs marketed under the 1906 Act if their conditions of use remained unchanged. (*Id.*)

b. In 1952, after Congress defined prescription drugs, the FDA announced it would not enforce the FFDCA for fluoridated public water

The Durham-Humphrey Amendment of 1951 (65 Stat. 648) for the first time explicitly defined two classes of medications (prescription and over-the-counter (“OTC”)). (Christopher v. SmithKline Beecham Corp., 635 F.3d 383, 385 (9th Cir. 2011).) In 1952, in response to this amendment, the FDA adopted a regulation stating:

- (a) The program for fluoridation of public water supplies recommended by the Federal Security Agency, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.
- (b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. . . .
- (c) The Federal Security Agency will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug, and Cosmetic Act.

(Former 21 CFR 3.27 (1952); 17 FR 6732; A 11.) This regulation was recodified to former 21 CFR 250.203 in 1975. (40 FR 13996; A 12.) It was published, as amended, in 1995. (A 13-14.)

c. In 1996 the FDA reversed its position to not enforce the FFDCA regarding fluoridated water after the EPA/FDA MOU was terminated and after Congress adopted the DSHEA that defined minerals as drugs if used to prevent specific diseases

In 1996, the FDA determined that its 1952 regulation was obsolete or no longer necessary and the regulation was revoked. (61 FR 29476; A 15.) The revocation of 21 CFR 250.203 occurred after the EPA announced the “Termination of the Federal Drinking Water Additive Program” effective

April 7, 1990. (53 FR 25586-89; CP 142-45; A 16-19.). The purpose of a 1979 MOU between FDA and EPA was having EPA operate the federal drinking water additive program. (44 FR 42775-78; CP 224-31.) EPA's announcement of termination of its additive program was effective notice to FDA that the 1979 MOU was terminated. (53 FR 42776, CP 225 "This [MOU] shall continue in effect unless . . . terminated by either party upon thirty (30) days advance written notice to the other.")

The revocation of 21 CFR 250.203 also occurred after the adoption by Congress of the Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417; "DSHEA"). This 1994 Act of Congress clarified Congressional intent that minerals including fluoride are drugs if the intended use is to prevent disease.

A dietary supplement is deemed to be " food," [21 U.S.C.] 321(ff), which is defined in part as "articles used for food or drink for man or other animals," *Id.* § 321(f)(1), except when it meets the definition of a "drug," which is defined in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

(Alliance for Natural Health U.S. v. Sebelius, 714 F.Supp.2d 48, 50 (D.D.C. 2010).) Under the DSHEA, dietary supplements include minerals. (21 U.S.C. 321(ff)(1)(B); A 22.) In adopting the DSHEA, Congress clarified its intent that fluoride mineral when used to prevent disease is a drug under federal law. The Commissioner of the FDA now concurs.⁴ (CP 352.)

⁴ Congress specifically asked FDA to address the relationship of "fluoride in drinking water and drug(s)." (CP 352.) The FDA responded, in part, stating "the Environmental Protection Agency regulates fluoride in the water supply." (*Id.*) But EPA had terminated its water additive program more than ten years earlier. (*Supra* at 14.) So FDA was referring to EPA regulating the Maximum Contaminant Level ("MCL") for fluoride that triggers clean-up under the SDWA and was not referring to fluoride additives or water with fluorides added.

d. The 1962 Amendments to the 1938 Act

The Congress amended the FFDCA in 1962 to change the standard for approval of a NDA or ANDA from “safe” to “safe and effective” for the intended use. (Samuels at 545.) For drugs with approved NDAs under the 1938 Act to retain these NDAs, they were required to demonstrate they were effective. (*Id.*; Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 612-15, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973).)

e. In 1972, the FDA established a new approval process for non-prescription drugs

In 1972, the FDA established a new approval process for non-prescription drugs. (21 CFR Part 330.) This process resulted in the establishment of over-the-counter (“OTC”) monographs for various drug classifications including a monograph for anticaries drug products that do not require a prescription. (21 CFR Part 355.) The final rule for the anticaries drug monograph and all amendments to date is provided in CP 147-91. This final rule, as amended, provides that all OTC anticaries drug products introduced to the market after April 7, 1997 must comply with general conditions in 21 CFR 330.1 and with anticaries monograph conditions in 21 CFR Part 355; otherwise a NDA or ANDA is required.

On or after [April 7, 1997] no OTC drug product that is subject to the monograph and that contains a nonmonograph condition . . . may be initially introduced . . . into interstate commerce unless it is the subject of an approved application or abbreviated application.

(CP 148 and 186.) Also, FDA regulations provide that any anticaries drug that includes hydrogen fluoride requires an NDA. (21 CFR 310.545(a)(2) and (b).)

2. **The Cities' fluoride additives are drugs under federal statute**

- a. **Citizens allege as a fact that Cities' fluorides are minerals intended for use in the prevention of dental caries (tooth decay) which is a disease in man**

Citizens have alleged as a fact that the Cities' fluorides are minerals intended for use in the prevention of dental caries (tooth decay) which is a disease in man. (*Supra* at 7.) Citizens allege that the primary, if not only, purpose identified for adding fluorides to public water supplies is to prevent dental caries. (CP 280-81, ¶ 6.)

- b. **Minerals, that are intended for use in the prevention of disease, are federal drugs**

Congress has adopted a specific statute that, under the facts of this case, designate the Cities' fluorides as drugs.

The term "drug" means

(A) articles recognized in the official United States Pharmacopoeia . . . ; and

(B) **articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and**

(C) articles (other than food) intended to affect the structure of any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C). . . .

(21 U.S.C. 321(g)(1); A 20-21; emphasis supplied.) The language quoted has not been amended since it was originally adopted in the 1938 Act. (52 Stat. 1041.)

- c. **The language in 21 U.S.C. 321(g)(1)(B) defining drugs should be interpreted by this Court "as broad as its literal language indicates"**

As early as 1916, the federal Supreme Court concurred that products that were otherwise defined as “foods” would be “drugs” under the federal statute⁵ when labeling for the substance includes statements of therapeutic (including preventative) effect. (Seven Cases v. United States, 239 U.S. 510, 513-14, 36 S.Ct. 190, 60 L.Ed. 411 (1916).)

After the 1938 Act was adopted, the federal Supreme Court again concurred that “food products” will be “drugs” based on “labeling.” (Kordel v. United States, 335 U.S. 345, 346, 69 S.Ct. 106, 93 L.Ed. 52 (1948).) In 1969, the federal Supreme Court, in finding a product was a drug, explained,

Congress intended to define “drug” [in 21 U.S.C. 321(g)(1)(B)] far more broadly than does the medical profession. . . . The word “drug” is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word.

(United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784, 793, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969).) The Bacto-Unidisk Court continued:

Congress fully intended that the Act’s coverage be as broad as its literal language indicates - and, equally clear, broader than any strict medical definition might otherwise allow. . . . the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act’s overriding purpose to protect the public health.

(*Id.* at 798.) The Bacto-Unidisk Court finally directed,

we must take care not to narrow the coverage of a statute short of the point where Congress indicated it should extend.

(*Id.* at 801.)

In the construction of federal statutes, “the decisions of the Supreme Court of the United States are binding” upon this Court. (Beezer v. City of Seattle, 62 Wn.2d 569, 573, 383 P.2d 895 (1963).) Therefore, this Court is

⁵ The relevant portion of the federal statute are quoted *supra* at 12.

required to construe the definition of drug as “articles intended for use in the . . . prevention of disease” as “broad as its literal language indicates.” (*Supra* at 17-18.)

d. “Intended use” of fluoride to prevent dental decay can be implied as a matter of law

Interpretation of federal statutes by other federal courts are entitled to great weight in this State. (*Beezer* at 573.) A long line of federal court cases has found that articles normally regulated as “foods” will be regulated as “drugs” if the intended use is to treat or prevent a disease:

The word “drug” is defined in 21 U.S.C. s 321(g)(1)(B) to include:

articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

Thus, it is the intended use of an article which determines whether or not it is a “drug,” and even the most commonly ingested foods and liquids are “drugs” within the meaning of the [FFDCA] if their intended use falls within the definition of s 321(g)(1)(B).

Gadler v. United States, 425 F.Supp. 244, 246-47 (D.Minn. 1977); *see Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983); *see also Bradley v. United States*, 264 F.79 (5th Cir., 1920) where the court specifically found “mineral water” to be a “drug” when it is intended to treat disease.

In the determination of whether the Cities’ fluorides are drugs,

the only question under the FFDCA is whether the intended use of the product is to prevent disease, not whether the product actually prevents disease.

(*United States v. Bowen*, 172 F.3d 682, 686 (9th Cir. 1999).) Intent “may be derived or inferred from [any] relevant source.” (*National Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325, 334 (2nd Cir. 1977).)

The FDA's interpretation of "intent" is entitled to "considerable deference." (Young v. Community Nutrition Institute, 476 U.S. 974, 981, 106 S.Ct. 2360, 90 L.Ed.2d 959 (1986).) The FDA finds that intended use "may be shown by the circumstances surrounding the distribution of the article." (21 CFR 801.4.) The FDA states:

in some instances, the mere presence of certain therapeutically active ingredients could make a product a drug even in the absence of drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g. fluoride in a dentifrice).

(59 FR 6088; A 24).

Citizens suggest that the intended use of fluorides in public water systems can also be implied to recognize these fluorides as drugs. The State Board of Health states,

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

(CP 124.) The Kaul Court accepted the fact, "That the addition of fluoride to the Chehalis water supply is intended solely for use in prevention of tooth decay." (Kaul at 353-54.)

- e. **The DSHEA further clarifies the intent of Congress that fluorides, which are minerals to be added to public drinking water to prevent the disease of dental caries, are a drug**

Perhaps partly in response to the FDA's refusal to enforce the FFDCA for fluoridated water supplies (*supra* at 13), Congress adopted the DSHEA in 1994, with explicit statutory language that made fluoride a drug when used with intent to prevent disease. Fluoride, being a mineral, is a dietary supplement under DSHEA. (21 U.S.C. 321(ff)(1)(B); A 22-23.) Minerals are normally regulated as foods except when they are drugs. (21 U.S.C.

321(ff) (“except for purposes of [21 U.S.C. 321(g) defining drugs] a dietary supplement shall be deemed to be a food;”) *supra* at 14.)

f. Congress did not exempt public water from the reach of federal drug laws

In 1974, Congress passed the Safe Drinking Water Act (“SDWA”). (88 Stat. 1661; codified at 42 U.S.C. 300f et seq.) The SDWA empowered the EPA to set standards for the control of contaminants in drinking water. (42 U.S.C. 300g-1(b); *see In re Groundwater Cases*, 154 Cal.App.4th 659, 677 (2007).) The SDWA authorizes EPA to adopt national primary drinking water regulations applicable to “public water systems.” (42 U.S.C. 300f(1); *see* 42 U.S.C. 300f(4)(A).) Under the SDWA, national primary drinking water regulations identify contaminants that have adverse effects on human health and specify a maximum contaminant level (“MCL”) for such contaminants. (42 U.S.C. 300f(1).) Pursuant to its authority under the SDWA, the EPA has since established MCLs for a wide variety of contaminants. (*See* 40 CFR Pt. 141 for substantive regulations, Pt. 142 for implementation regulations, and Pt. 143 for national secondary drinking water regulations that are not enforceable.) The fluoride MCL is 4.0 mg/l (one milligrams per liter equals one part per million (“ppm”). (40 CFR 141.62(b)(1).)

But there is no SDWA statutory provision or implementing regulation that addresses or sets standards for fluoride water additives.⁶ (SDWA; 40

⁶ There is a SDWA statutory provision that directs the EPA to keep away from regulating drugs. (42 U.S.C. 300g-1(b)(11) (“No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.”))

CFR Part 141 et seq.) Therefore, there is no possible statutory conflict where Congress intended the SDWA to interfere with the FFDCA or FDA authority to regulate drugs. If Congress wanted to exempt public drinking water from the definition of drugs in 21 U.S.C. 321(g)(1)(B) it certainly had the knowledge of how to do it (it had previously exempted “food” from subsection (1)(C)) and it certainly had the opportunity to do it in any one of the more than 20 significant amendments made to the FFDCA since 1980. (A 25-26.) The SDWA did not explicitly or implicitly repeal any drug provision of the FFDCA or any drug authority of the FDA.

g. The 1979 MOU, addressed in dicta in City of Port Angeles, has been terminated but never did restrict FDA authority over drugs

i. The 1979 MOU

In 1979, EPA and FDA entered into an MOU where FDA agreed not to enforce its food authority over public drinking water in exchange for EPA creating a federal regulatory drinking water additives program. (CP 224-31; *supra* at 14.) In the FFDCA, Congress gave FDA authority to regulate foods to ensure they are “safe” (21 U.S.C. 393(b)(2)(A)) and drugs to ensure they are “safe and effective” (21 U.S.C. 393(b)(2)(B)). Normally for drinking water, only food regulations would be applicable and prior to 1979, the FDA generally regulated drinking water as a food. (CP 224.) But after passage of the SDWA, EPA and FDA were concerned that FDA’s “food” authority and EPA’s “public drinking water” authority might result in “duplicative and inconsistent regulations” so they entered an MOU. (*Id.*) In the MOU, FDA agreed not to use its “food” authority to regulate public drinking water, based

on a commitment that EPA would adopt regulations to control additives in public drinking water. (CP 224-25.)

There is no mention in the MOU that FDA would, or could, give up its “drug” authority over public drinking water and public drinking water additives. Congress required “drugs” to be “effective” (21 U.S.C. 393(b)(2)(B)) and Congress never gave EPA authority to regulate drug effectiveness. The MOU inartfully states:

[EPA and FDA] 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.

CP 224. Read in context with the other provisions of the MOU this can only possibly be true with respect to FDA’s “food” authority and cannot be true with respect to FDA’s “drug” authority. (CP 224-25; *See Board of Governors of the Federal Reserve System*, 474 U.S. 361, 368, 106 S.Ct. 681, 88 L.Ed.2d 691 (1986) (“agency interpretation” cannot “alter the clearly expressed intent of Congress.”))

In a subsequent section, the MOU states:

[EPA and FDA] agreed that the Safe Drinking Water Act’s passage in 1974 implicitly repealed FDA’s jurisdiction over **drinking water as a “food”** under the [FFDCA].

CP 225 (emphasis supplied). Thus the MOU itself clarifies that the MOU only impacts FDA’s “food” regulations. The MOU also inartfully states:

Under the agreement, EPA now retains exclusive jurisdiction over drinking water served by public water supplies, including any additives in such water.

CP 225. In context of the whole agreement, EPA does not have exclusive jurisdiction when public drinking waters, including any additives in such

waters, are “drugs” because Congress has given exclusive jurisdiction over drugs to the FDA. (21 U.S.C. 393(b)(2)(B); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000).) Congress has clearly defined “drugs” in 21 U.S.C. 321(g)(1). Further EPA claims no authority that would give it jurisdiction over the determination of “effectiveness” of drugs. (CP 224-27.)

ii. The 1979 MOU is terminated

In 1988, EPA published in the Federal Register a “Notice” that it was terminating its commitment to FDA to create a federal regulatory drinking water additives program. (53 FR 25586-89; A 16-19.) In this 1988 Notice EPA admitted that it “does not currently regulate the levels of additives in drinking water.” (A 16.) It explained that the “SDWA does not require EPA to control the use of specific additives in drinking water.” (A 16.) It states,

Resource constraints and the need to implement mandatory provisions of the SDWA precluded the Agency from implementing the comprehensive program originally envisioned
...

(A 17.) The notice describes how EPA was cooperating with a private third-party organization to have that organization take over the development and monitoring of standards for public drinking water additives and explained that it would be “up to the States and utilities to determine the suitability of any ‘third-party’ certification.” (A 16-18.) Then it announced that effective April 7, 1990, it would withdraw all EPA and predecessor agency lists of acceptable water additive products and all EPA and predecessor agency advisory opinions on drinking water additives. (A 19.) EPA stated that

“Discontinuance of the additives program at EPA does not relieve the Agency of its statutory responsibilities.” (A 19.)

EPA’s Federal Register published Notice that it was terminating its commitment to FDA to create a regulatory federal drinking water additives program was effective notice to FDA that EPA was exercising its option to terminate the MOU. (*Supra* at 14.) Thus the 1979 MOU was terminated in 1990 and EPA removed the cloud over FDA’s “food” jurisdiction regarding public fluoridated water. FDA never lost “drug” jurisdiction over fluoridated water, but its policy, that it would not enforce this jurisdiction, remained in effect from 1952 to 1996. (*Supra* at 13-14.)

h. The intent of Congress clearly establishes that the Cities’ fluorides are drugs under the FFDCA

In 1916, the federal Supreme Court concurred that Congress in adopting the 1906 Act directed that food be regulated as a drug when therapeutic (including preventative) effects are intended. (*Supra* at 17.) In the 1938 Act, Congress significantly broadened, instead of limited, the definition of drugs. (*Compare supra* at 12 and 16.) In 1948, the federal Supreme Court again concurred “food products” will be “drugs” depending on “labeling.” (*Supra* at 17.)

In 1952, the FDA stated it would not enforce the FFDCA for fluoride added to public water supplies. (*Supra* at 13.) In 1969, the federal Supreme Court ruled that the FFDCA definition of drugs is “as broad as its literal language indicates.” (*Supra* at 17-18.) In 1994, the Congress again specifically clarified that minerals will be drugs if they fall within the broad definition of drugs. (*Supra* at 14.) In 1996, the FDA revoked its policy that

it would not enforce the FFDCA for fluoride added to public water supplies. (*Supra* at 13-14.)

This Court is bound by the intent of Congress as explained by the federal Supreme Court. (*Supra* at 17.) Therefore, Citizens request this Court to find, at a minimum, that under the alleged facts, the Cities' fluorides would be federal drugs. But because this Court can find as a matter of law that fluorides' therapeutic use can be implied, Citizens would prefer that this Court find as a matter of law that the Cities' fluorides are federal drugs.

3. The Cities' fluoridated waters are drugs under federal statute

Citizens incorporates by reference the argument in subsection B.2 above to show that the fluorides added to the Cities' public water supplies are drugs under federal statutes. In this subsection, Citizens will show that the resulting fluoridated waters are federal drugs as well.

a. Citizens allege as a fact that the Cities' fluoridated waters are intended for use in the prevention of dental caries (tooth decay) which is a disease in man

Citizens allege as a fact that the Cities' fluoridated waters are intended for use in the prevention of dental caries (tooth decay) which is a disease in man. (*Supra* at 7.)

b. The Cities use their public water systems to distribute federal fluoride drugs to their customers with intent that the fluoridated water will prevent dental caries

The Cities use their public water systems to supply fluoride drugs to customers and other people who consume the Cities' fluoridated waters. These fluoridated waters are a food under 21 U.S.C. 321(f) ("used for food

or drink for man or other animals”). (A 20.) But the federal Supreme Court has found that “foods” are to be treated as “drugs” when, as here, there is intent to prevent disease. (*Supra* at 17.) The drug definition in 21 U.S.C. 321(g)(1)(B) is to be interpreted “as broad as its literal language indicates.” (*Supra* at 17-18.) Therefore because fluoridated waters are intended to prevent the disease of dental caries, this Court should find that these “foods” must be regulated as “drugs” under federal law.

c. Waters that have fluoride, but no fluoride added, are not regulated as drugs

Waters that have fluoride, but no fluoride added, would not be regulated as drugs unless it is established that there is an intent to prevent disease. Fluoridated drinking water (fluoride added to water) is a drug because the intent of adding the drug fluoride is sufficient evidence that there is intent to use the product to prevent dental caries disease.

d. The Cities’ public water systems operate in interstate commerce so federal drug laws apply

By federally-regulating all public water systems in all states with the adoption of the SDWA, Congress declared its intent that all such public water systems are in interstate commerce and therefore federal drug laws apply to water additives for these systems. Also for Washington State, the record shows that all City fluorides were manufactured out-of-state. (CP 376-80.)

e. Failure of the FDA in the past to enforce its statutory authority over fluoridated waters and fluoride additives does not deprive the FDA of jurisdiction

FDA statutory jurisdiction to regulate fluoridated waters and fluoride additives as drugs is granted by the clear intent of Congress as interpreted by

the federal Supreme Court. Agency interpretations cannot alter the clearly expressed intent of Congress. (*Supra* at 22.)

f. “Intended use” of fluoridated water to prevent dental decay can be implied as a matter of law

Using the same argument used in subsection B.2.d. above, which is incorporated herein by reference, this Court is requested to conclude that the intended use of fluoridated water to prevent dental decay can be implied as a matter of law.

g. The intent of Congress is clear that the Cities’ fluoridated waters are drugs under the FFDCA

Rather than repeating the arguments made in subsection B.2.h. above, Citizens hereby incorporates that argument by reference into this subsection. Relevant to this subsection, Citizens request this Court to find, at a minimum, that under the alleged facts, the Cities’ fluoridated waters would be federal drugs. But because this Court can find as a matter of law that fluoridated waters’ therapeutic use can be implied, Citizens would prefer that this Court find as a matter of law that the Cities’ fluoridated waters are federal drugs.

4. Review of State drug laws and regulations

a. The relevant State statutory definitions of drugs are essentially the same as the federal statutory definition of drugs

The relevant federal definition of drugs in 21 U.S.C. 321(g)(1)(B) is:

Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

All of our State definitions of drugs are effectively the same:

Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;

RCW 69.41.010(9)(b);

articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

RCW 69.04.009(2); and

Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;

RCW 18.64.011(11)(b).

The language in RCW 69.41.010(9)(b) was first adopted in Laws of 1973, 1st Ex. Sess., ch. 186, § 1, with the only change being that the phrase “human beings” was then “man.” Section -.010 was amended 15 times. The language in RCW 69.04.009(2) was adopted in Laws of 1945, ch. 257, § 10 again with the only change being that the phrase “human beings” was then “man.” Section -.009 was changed only once. The language in RCW 18.64.011(11)(b) was first adopted in Laws of 1963, ch. 38, § 1, with the only two changes being that the phrase “human beings” was then “man” and the word “Substances” was then “Articles.” Section -011 was amended 6 times.

b. One State statutory definition of legend drugs was revised to give fair notice of conduct forbidden by penal statutes

i. Original State definitions of legend drugs

The statutory definition of legend drugs first appears in Laws of 1973, 1st Ex. Sess., ch. 186, § 1, and the definition was:

“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).)

ii. The establishment of an independent State Board of Pharmacy

This State Board of Pharmacy was first established by Laws of 1891, ch. CLIII, § 5. Its powers were given to the director of licenses and the board was abolished in Laws of 1921, ch. 7, § 96 and § 135. This Board was reestablished in Laws of 1935, ch. 98, § 1 (and given authority to adopt rules in § 3). This Board is independent from other agencies but uses the Department of Health for staff assistance. RCW 18.64.310. Today the powers and duties of this Board include:

Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare . . .

(RCW 18.64.005(7); Laws of 1979, ch. 90, § 2.)

iii. Legend drug definitions were revised to give fair notice of conduct forbidden by penal statutes

The original definition of legend drugs in former RCW 69.41.010(8) was challenged in State v. Jordan, 91 Wn.2d 386, 588 P.2d 1155 (1979). The Board of Pharmacy adopted a regulation effective June 18, 1976 to make possession of legend drug ephedrine without authorization a crime. (Jordan at 387.) Six days after the effective date, Jordan was arrested while shipping and receiving boxes of ephedrine without required authorization. (*Id.* at 387-88.) Jordan claimed “lack of fair notice of conduct forbidden by penal statutes.” (*Id.* at 388-89.) The Jordan Court reviewed former RCW 69.41.010(8) and concluded it was unconstitutional in criminal proceedings because of its,

failure to indicate those agencies with authority to designate legend drugs and resultant failure to give fair notice of the conduct it proscribes.

(Jordan at 390.) In Laws of 1979, 1st Ex. Sess., ch. 139, § 1, the Legislature modified the definition of legend drugs in Chapter 69.41 RCW to the current definition, adding a notice identifying the agency with authority:

“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 64.41.010(12). Also in Laws of 1979, ch. 90, § 5, the Legislature put the former definition of legend drugs from former RCW 69.41.010(8) into Chapter 18.64 RCW where it remains unamended in RCW 18.64.011(14).

iv. Current State Board of Pharmacy Regulations defining legend drugs

The Board of Pharmacy has adopted three regulations that can be used to determine if a drug is a legend drug: WAC 246-879-010 (A 33-34); WAC 246-883-020(1) (A35-36); and WAC 246-883-020(2) (A 35-36). These regulations will be discussed in later sections of this brief.

5. The Cities’ fluorides and fluoridated waters are drugs under State statutes

a. **Because the Cities’ fluorides and fluoridated waters are drugs under federal statute they should be drugs under state statutes because the relevant definition is the same in State and federal statutes**

State statutes have essentially the same definitions for drugs as do the federal statutes. (*Supra* at 27-28.) In such a case, the federal Supreme Court’s interpretation of the similar federal statute is persuasive although not controlling authority as to the way this Court should interpret the State statutes. (Aviation West Corp. v. Washington State Dept. Of Labor and

Industries, 138 Wn.2d 413, 424, 980 P.2d 701 (1999).) In the instant case, regarding the definition of the term “drug,” there is no reason not to use the federal court interpretations.

The legislature, by adopted the federal definition of drugs in multiple locations, indicated its intent to have the same set of substances be considered drugs under both federal and state statutes. Congress makes findings in 21 U.S.C. sections 321, 352, 360, and 801 that drugs move freely between interstate and intrastate commerce so uniform controls are necessary for public safety. Therefore if this Court finds fluorides and fluoridated waters are drugs under federal law, it should find them to be drugs under state laws.

b. There is no State drinking water statute that is in conflict with Legislative intent to have the Cities’ fluorides and fluoridated waters regulated as drugs

Assuming that this Court finds the Cities’ fluorides and fluoridated waters are federal drugs, the fluoride manufacturers and Cities will be required to register annually with the FDA. (21 U.S.C. 360.) The FDA is directed to ensure that these drugs are safe and effective to protect the public health. (21 U.S.C. 393(b)(2)(B).) When the manufactures and Cities register, FDA will give them instructions if any other actions must be taken.

If the Cities’ fluoridated waters are State drugs, the Cities will be required to get a license pursuant to RCW 18.64.045 from the Department of Health because they will be drug manufacturers pursuant to RCW 18.64.011(16). The Cities will have to comply with good manufacturing practices. (Chap. 246-896 WAC.) The public will have the drug protections envisioned by the Congress and the Legislature.

The Legislature has given responsibility to the State Board of Health to adopt rules for public water systems “to assure safe and reliable public drinking water and to protect the public health.” (RCW 43.20.050(2)(a);⁷ A 27-29.) These rules have to followed by the Cities. The Legislature has also given responsibility to the State Board of Health to adopt rules for state implementation of the SDWA. (See Chap.70.142 RCW.) The Legislature has given responsibility to the State Board of Pharmacy to establish rules for the manufacturing and distribution of drugs. (RCW 18.64.005; A 30.) There is no authority for the State Board of Health to adopt rules regarding manufacturing and distribution of drugs because this authority has been given specifically to the State Board of Pharmacy. The State Board of Pharmacy is the only agency with the experience with drugs that is necessary to protect the public from drug mismanagement. While there is an overlap of authority between the State Board of Health and the State Board of Pharmacy, if the Cities use police power to put federal and state drugs in their public water systems, there is no conflict with State statutes.

C. The Trial Court Abused Discretion When It Denied Citizens’ Motion To Amend Complaint

1. Citizens’ motion to amend complaint was denied by the trial court finding it was futile because the trial court believed it would have to overrule Kaul

Citizens brought a Motion to Amend Complaint to add a declaratory judgment requesting the trial court to “declare that the Cities’ fluoridated

⁷ The State Board of Health and the State Department of Health are not in the same agency although the Secretary of Health (see RCW 43.70.130) is a member of the Board of Health and runs the Department of Health. The State Board of Health adopts public water safety regulations and the State Department of Health administers those regulations. RCW 70.119A.060(3)

waters and/or the bulk fluoride products used to make these waters are drugs.” (CP 200-04; *Supra* at 8.) In its motion, Citizens pointed out that the Court would be considering this issue in the pending Cities’ Motion to Dismiss that was being heard on the same day and that Citizens’ wanted a clear ruling as to whether the Cities’ fluorides and fluoridated waters are drugs. (CP 201-02.) Citizens also pointed out that Citizens “could be barred by res judicata from bringing this Declaratory Judgment issue if the issue is not resolved in the instant case.” (CP 201.) The trial court considered the motion and ruled that Kaul established precedent that these substances were not drugs and that the trial court would have to overrule this Supreme Court case to find otherwise. (A 8; *supra* at 1) The trial court found the amendment futile because he could not overrule Kaul. (A 6.)

2. **Citizens’ motion was not futile because the Cities’ fluorides and/or fluoridated waters are drugs**

Citizens’ motion is not futile because, under the alleged facts, the Cities’ fluorides and/or fluoridated waters are drugs as demonstrated in the record before the trial court and as demonstrated to this Court in this brief. Because the request was not futile, the trial court exercised its discretion on untenable grounds and for untenable reasons.

3. **Citizens’ motion was denied on untenable grounds and for untenable reasons because it relied on dicta that need not be followed**

In oral argument, Citizens told the trial court that the “comment about drugs in Kaul is dicta.” (RP 9.) The holding in Kaul is that the City of Chehalis had constitutional police power authority to fluoridate. (Kaul at 619 and 625; *supra* at 1.) After reaching this holding, the Kaul Court summarily

rejected, as irrelevant to its constitutional determination, a claim that the City was selling drugs. (*Supra* at 1.) The trial court exercised its discretion on untenable grounds and for untenable reasons when it relied on this dicta to find the issue futile because dicta need not be followed. (*Gerberding v. Munro*, 134 Wn.2d 188, 224, 949 P.2d 1366 (1998) (“That which is beyond, or not necessary to, this holding is dicta. Dicta is not controlling authority and need not be followed.”); *supra* at 1.)

4. **This Court should find that the trial court abused discretion and this Court should issue its opinion as a matter of law, or on alleged facts, that the Cities’ fluorides and fluoridated waters are drugs**

This Court should find that the trial court abused discretion and this Court should issue its opinion as a matter of law, or on alleged facts, that the Cities’ fluorides and fluoridated waters are drugs.

D. **The Cities’ Fluorides And Fluoridated Waters Are Federal Prescription Drugs**

Under federal law, if the City of Forks’ bulk fluorides are federal drugs, they clearly are prescription drugs because of their toxicity and package quantity. (*See* CP 327-36 and 340-45.) Bulk sodium fluoride for the City of Forks comes in 50 pound bags. (CP 280, ¶ 5.) The 2009 Drug Topics Red Book show that bulk sodium fluoride in package sizes of 125 grams (about 1/4 pound) and larger are included in its prescription drug list. (A 31; CP 43 (lower right corner of page).) Bulk fluorosilicic acid for the City of Port Angeles comes in 24,060 pound tanker truck deliveries. (CP 280, ¶ 5.) This is not an OTC drug.

The Cities' fluoridated waters are not OTC drugs because with the chemicals used today they were first made after April 7, 1997. (*Supra* at 7.) All OTC anticaries drug products introduced to the market after April 7, 1997 must comply with general conditions in 21 CFR 330.1 and with anticaries monograph conditions in 21 CFR Part 355; otherwise a NDA or ANDA is required. (*Supra* at 15.) The Cities' fluoridated waters do not meet the anticaries monograph conditions in 21 CFR Part 355 (21 CFR 355.1 et seq.; *see* CP 182-83.) because their fluoridated waters are intended to be swallowed and there are no monograph OTC drugs that can be swallowed except under 21 CFR 355.60 and products in this section are restricted to use by practitioners only. City water customers do not only drink water in a practitioner's office.

So because the Cities' fluoridated waters were first made with the current formulations after April 7, 1997, and because they do not meet anticaries monograph conditions, and because they do not have approved NDAs or ANDAs (*supra* at 7), they cannot be OTC drugs. (*Supra*.) Therefore under federal laws and regulations, the Cities' fluorides and fluoridated waters are federal prescription drugs.

E. The Cities' Fluorides And Fluoridated Waters Are State Prescription Drugs And State Legend Drugs

Pursuant to a regulation adopted by the State Board of Pharmacy, any drug that is a federal prescription drug is also a state prescription drug. (WAC 246-879-010(9); A 32-33.) Under RCW 18.64.011(14),

“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.

Therefore, because the Cities' fluorides and fluoridated waters are prescription drugs under federal laws and regulations, they are legend drugs under RCW 18.64.011(14).

F. The Cities' Fluorides And Fluoridated Waters Are State Legend Drugs Under RCW 69.41.010(12)

1. The Cities' fluorides are legend drugs under RCW 69.41.010(12) independent of WAC 246-883-020

The Cities' fluorides are also State 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.

Because the Cities' fluorides are State prescription drugs under WAC 246-879-010(9) which is a “regulation of the State Board of Pharmacy,” (*Supra* at 35.) they are legend drugs under RCW 69.41.010(12). It makes sense to interpret these regulation and laws in this manner because Citizens is bringing a civil complaint and not a criminal complaint as was brought in State v. Jordan, 91 Wn.2d 386, 588 P.2d 1155 (1979).

2. The Cities' fluorides are also legend drugs under RCW 69.41.010(12) pursuant to WAC 246-883-020(1)

Another regulation of the State Board of Pharmacy is WAC 246-883-020(1) which states:

In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

This regulation finds that if the FDA makes a substance a prescription drug then it “should” also be a prescription drug in Washington State. The word “should” used in this regulation is ambiguous. “Should” is defined as the 1) “past tense of shall,” 2) “(used to express condition)”, and 3) “must.” Webster’s New Universal Unabridged Dictionary (2003). In the context of this regulation, and to be consistent with RCW 18.64.011(14) and WAC 246-879-010(9), the word “should” is best interpreted to be “must” such that if the FDA makes a substance a prescription drug, then it is a prescription drug under this State Board of Pharmacy regulation. The Cities cannot claim the lack of notice that was fundamental in *Jordan* (*Supra* at 29-30.) because the Cities were given notice when Citizens’ complaint was served on them in April, 2011. WAC 246-883-020(1) is a “regulation of the State Board of Pharmacy,” and pursuant to this regulation, the Cities’ fluorides are legend drugs under RCW 69.41.010.

3. The Cities’ fluorides are also legend drugs under RCW 69.41.010(12) pursuant to WAC 246-883-020(2)

Yet another regulation of the State Board of Pharmacy is WAC 246-883-020(2) which states:

For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2009 edition of the Drug Topics Red Book. . . .

This regulation of the State Board of Pharmacy should be viewed as an alternative regulation that will withstand criminal constitutional challenges and was likely provided by the State Board of Pharmacy just for that purpose. Because this is a civil action, it is not necessary to read this regulation as the “only way” that RCW 69.41.010(12) can be interpreted.

WAC 246-883-020(2) add a requirement of a listing in the Red Book. What constitutes a “listing?” Is the intent to only include specific brands of products in specific retail size packages, or to cover, and thus to be able to regulate, all replacement brands for the same product in any quantity? Only the latter interpretation allows reasonable protection of public health, which surely was the legislative intent. Bulk sodium fluoride is listed in the Red Book in 1/4 pound to 10 pound packages. (A 31; CP 43-44.) That should also cover 50 pound packages. (See CP 360 where the Board simply found bulk fluoride is a legend drug under RCW 69.41.) Fluorosilicic acid is substitute source of the active fluoride ion. (See 21 CFR 355.3; CP 122.) In bulk quantities, its listing in the Red Book is implied under a broad interpretation of intent to regulate toxic drugs.

4. **The Cities’ fluoridated waters distribute drugs that are legend drugs under RCW 69.41.010(12)**

In State v. Keating, 30 Wn. App. 829, 833, 638 P.2d 624 (1979), Div. 3 ruled that in a criminal case for possession and delivery, the State had to prove the ephedrine found was not from an OTC source. The instant case is not a criminal case, but we know that fluorides being delivered in the fluoridated waters are from a legend drug source and we know the Cities are selling these legend drug fluorides in their fluoridated waters that they manufacture.

G. **This Court Should Overrule, Clarify, Or Distinguish Kaul and City of Port Angeles**

Citizens request this Court to overrule, clarify, or distinguish Kaul and City of Port Angeles to the degree that these cases hold or imply that municipal fluoridated waters, and their bulk fluoride products, cannot be or

are not drugs. Citizens argues that the mention in Kaul at 625 regarding selling drugs and the mention in City of Port Angeles at 592, n. 1 that the FDA doesn't regulate public drinking water are both dicta that need not be followed. (*Supra* at 1-2, 33-34.)

If it is necessary for the Supreme Court to overrule rather than clarify these statements, it should do so because as this brief demonstrates the statements are wrong and harmful. (State v. Berlin, 133 Wn.2d 541, 547-48, 947 P.2d 700 (1997) (Decision overturned was "both incorrect and harmful.") It is harmful because half of people in this State are taking a drug with adverse side effects (CP 235-37) that is supplied in violation of drug regulations.

H. This Court Should Find WAC 246-290-220(3) And WAC 246-290-460(2), -(3)(b)(iv)(A) violate U.S. Const. Art. VI, cl. 2

This Court should find that two provisions of Ch.246-290 WAC violate U.S. Const. Art. VI, cl. 2 (Supremacy Clause). Congress has given the FDA responsibility to approve drugs and dosage rates before drugs can be marketed. (*Supra* at 16.) Federal law occupies this field. WAC 246-290-220(3) (A 34) on its face and as applied requires the Cities who fluoridate to use ANSI/NSF Standard 60 fluorides at dosing rates specified in WAC 246-290-460(2) and -(3)(b)(iv)(A) (A 35-36). But this is in direct conflict with FDA authority to approve fluorides as drugs and set dosing rates for each drug. Until the FDA acts, the Act of the Board of Health to approve drugs and set dosing rates hinders the objective of the federal law, and creates direct conflicts where Congress and FDA occupy the field. (*Supra* at 10-11.) Federal law for these substances prohibits marketing without pre-approval.

I. Request For Statutory Attorney Fees and Costs

Citizens requests statutory attorney fees and costs pursuant to RCW 4.84.020 and -.080 if it prevails on this appeal.

VI. CONCLUSION

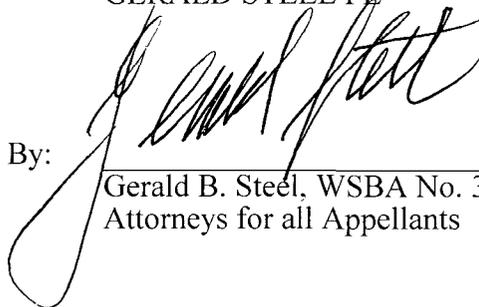
Citizens requests that this Court find that the Cities' fluorides and fluoridated waters are federal and state, drugs and prescription drugs, and state legend drugs under RCW 69.41.010(12). Citizens requests that the Dismissal Motion and the Order denying amendment be reversed and the identified WACs be invalidated either by section or subsection.

Dated this 17th day of November, 2011.

Respectfully submitted,

GERALD STEEL PE

By:



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

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STATE OF WASHINGTON

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CERTIFICATE OF SERVICE
OF ROLAND CARPENTER

I certify that on the 17th day of November, 2011, I caused a true and correct copy of this Certificate and Brief of Appellants to be served on the following by first class mail:

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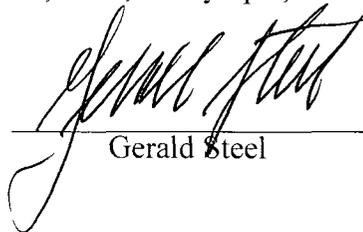
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Forks, WA 98331

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Supreme Court State of Washington
P.O. Box 40929
Olympia WA 98504-0929

Dated this 17th day of November, 2011, at Olympia, Washington.



Gerald Steel

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APPENDIX INDEX

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IN SUPERIOR COURT
JEFFERSON COUNTY CLERK

SUPERIOR COURT OF WASHINGTON IN AND FOR CLALLAM COUNTY

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

Petitioners,

v.

CITY OF PORT ANGELES, and CITY OF
FORKS ,

Defendants.

The Honorable Craddock Verser,
Visiting Judge
Hearing Date: June 17, 2011 @ 1:00 PM

No. 11-2-00433-6

ORDER GRANTING DEFENDANT
CITIES' MOTION TO DISMISS

~~XXXXXXXXXX~~

This matter came before the Court on Defendant Cities' Motion To Dismiss (the "Motion") brought by Defendants City of Port Angeles and City of Forks (the "Cities"). The Court read and considered the pleadings and files in this action, the Motion, the responding materials from Petitioners, and the reply materials from Defendants. The Court also heard and considered argument of counsel for both parties. Deeming itself fully advised, the Court finds as follows:

1. The Cities each operate a public drinking water utility.
2. The Cities each provide a fluoridation program for their public drinking water utility.
3. In the Complaint in this action, the plaintiffs ask the Court to issue a search and seizure warrant under RCW 69.41.060 to seize the Cities fluoridation systems and any bulk

ORDER GRANTING DEFENDANT CITIES' MOTION
TO DISMISS - 1

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1 fluoridation additives used in connection with those systems. Plaintiffs claim that the
2 Cities' fluoridated drinking water and those fluoridation additives are "legend drugs"
3 requiring a prescription under Chapter 69.41 RCW and that are being distributed in
4 violation of that chapter.

5
6 4. The Washington Supreme Court held in *City of Port Angeles v. Out Water--Our Choice*,
7 170 Wn.2d 1 (2010) that under federal law the U.S. Environmental Protection Agency
8 ("EPA") regulates public drinking water and allows for greater state regulation; the
9 Washington Legislature vests the Department of Health with state regulatory authority;
10 that the Washington Department of Health regulations permit public water systems (such
11 as the Cities' systems) to adopt a water fluoridation program; the Department of Health
12 regulations include a specific regulation of fluoride; and the Department of Health
13 specifically permits fluoride additives to public drinking water systems.

14
15 5. The U.S. Food and Drug Administration is the federal agency regulating all prescription
16 drugs. The FDA has given notice in the Federal Register that it does not regulate public
17 drinking water or additives to public drinking water; and the Supreme Court in *City of*
18 *Port Angeles* confirmed that the FDA does not regulate public drinking water or additives
19 to public drinking water.

20
21 6. In order to be classified as a "legend drug" for purposes of Chapter 69.41 RCW, the
22 Washington Board of Pharmacy regulations require that a drug must meet two
23 requirements: a) it must be classified as a legend drug under federal law; and b) it must
24 be listed as such in the 2009 edition of the *Drug Topics Red Book*. WAC 246-883-020.
25
26

ORDER GRANTING DEFENDANT CITIES' MOTION
TO DISMISS - 2

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1 7. Because the FDA does not regulate public drinking water or drinking water additives, it
2 is impossible for plaintiffs to prove that the first requirement for being a "legend drug"
3 under Washington law is met.

4 8. The Complaint and the attachments thereto show that neither public drinking water nor
5 fluoridation additives to public drinking water are listed as a legend drug in the 2009
6 edition of the *Drug Topics Red Book*. Therefore, it is also impossible for plaintiffs to
7 prove that the second requirement for being a "legend drug" under Washington law is
8 met.

9 9. Accordingly, there is no set of facts plaintiffs can prove that would show the Cities'
10 public drinking water or the Cities' fluoride additives for drinking water fluoridation (as
11 permitted by the Department of Health) are legend drugs, and the Complaint should be
12 dismissed pursuant to CR 12(b)(6).

13 ~~10. Plaintiffs and their counsel were well aware of the decision of the Washington Supreme
14 Court providing that fluoride additives to public drinking water are permitted by the
15 Washington Department of Health. Plaintiffs and their counsel are also well aware of the
16 definition of "legend drugs" in WAC 246.883-020 and cited that regulation in the
17 Complaint. Plaintiffs were aware that neither requirement of that definition was met
18 because fluoride additives to public drinking water are not classified as "legend drugs"
19 under federal law and because fluoride additives to public drinking water are not listed
20 legend drugs in the 2009 edition of the *Drug Topics Red Book*.~~

21 ~~11. Accordingly the claim brought in the Complaint is not well grounded in fact or warranted
22 by existing law or a good faith argument for the extension, modification or reversal of~~

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ORDER GRANTING DEFENDANT CITIES' MOTION
TO DISMISS - 3

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1 existing law as required by Civil Rule 11. The claim brought in the Complaint is also
2 frivolous and meritorious for purposes of RCW 4.84.185.

3 12. It is appropriate to award terms under CR 11 and RCW 4.84.185 in order to protect the
4 ratepayers of the City of Port Angeles and City of Forks utilities from this type of
5 vexatious and meritorious litigation.
6

7 Based on the foregoing findings, it is accordingly ORDERED, ADJUDGED and DECREED as
8 follows:

9 A. Plaintiffs' Certified Complaint For Search And Seizure Warrants should be, and hereby
10 is, DISMISSED WITH PREJUDICE.

11 B. ~~Defendants City of Port Angeles and City of Forks are hereby awarded their costs and~~
12 ~~reasonable attorneys fees expended in the defense of this action pursuant to CR 11 against~~
13 ~~Petitioners and Petitioners' counsel jointly and severally.~~

14 C. ~~Defendants City of Port Angeles and City of Forks are hereby awarded their costs and~~
15 ~~reasonable attorneys fees expended in the defense of this action pursuant to RCW 4.84.185~~
16 ~~against Petitioners jointly and severally.~~

17 D. ~~Defendants shall present a Cost Bill for consideration of the Court pursuant to Court~~
18 ~~Rule.~~

19
20 DATED this 17 day of June 2011.

21
22
23 
24 HON. CRADDOCK VERSER, Superior Court
25 Judge
26

ORDER GRANTING DEFENDANT CITIES' MOTION
TO DISMISS - 4

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17 and City of Forks

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ORDER GRANTING DEFENDANT CITIES' MOTION
TO DISMISS - 5

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BARBARA CHRISTENSEN CLERK

SUPERIOR COURT OF WASHINGTON IN AND FOR CLALLAM COUNTY

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

Petitioners,

v.

CITY OF PORT ANGELES, and CITY OF
FORKS ,

Defendants.

The Honorable Craddock Verser,
Visiting Judge
Hearing Date: June 17, 2011 @ 1:00 PM .

No. 11-2-00433-6

ORDER DENYING MOTION TO
AMEND COMPLAINT

This matter came on regularly before the Court on June 17, 2011, on the Motion to Amend Complaint ("Motion") brought by Petitioners Protect the Peninsula's Future, Clallam County Citizens for Safe Drinking Water, and Eloise Kailin. The Court read and considered the pleadings and files in this action, the Motion, and the responding materials from Defendants. The Court also heard and considered argument of counsel for both parties. Deeming itself fully advised, the Court: finds that the amendment to the Complaint would be futile for the reasons described by Judge Verser in the record.

ORDERED, ADJUDGED and DECREED as follows:

Petitioners' Motion to Amend Complaint should be, and hereby is, DENIED.

//

ORDER DENYING MOTION TO AMEND
COMPLAINT - 1

COPY

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DATED this 23rd day of June 2011.

Judge Craddock Verser

HON. CRADDOCK VERSER, Superior Court
Judge

Presented by:

WILLIAM E. BLOOR, City Attorney,
City of Port Angeles

Roger A Pearce for
William E Bloor, WSBA #4084

WILLIAM R. FLECK, City Attorney,
City of Forks

Roger A Pearce for
William R Fleck, WSBA #23962

FOSTER PEPPER PLLC

Roger A Pearce
P. Stephen DiJulio, WSBA #7139
Roger A. Pearce, WSBA #21113
Attorneys for defendants City of Port Angeles
and City of Forks

Agreed as to form; notice of presentation waived.

GERALD STEEL, PE

Gerald Steel
Gerald Steel, WSBA # 31084
Attorney for petitioners Protect the Peninsula's
Future, Clallam County Citizens for Safe Drinking
Water, and Eloise Kailin

ORDER DENYING MOTION TO AMEND
COMPLAINT - 2

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AT

3 1 and the Board of Health. Those are two independent boards.
2 They have the authority to make rules. The Board of -- the
3 Department of Health has no authority to make rules on these
4 matters.

4 5 THE COURT: Okay. I've read the Kaul case as
6 well, and I -- and I would have to be overruling a Supreme
7 Court case to find -- to grant -- I mean -- all right. All
8 you've done is move to amend. You're right. Amendments
9 should be freely given, except when the amendment is futile.
10 In that case to me, Mr. Steel, that's right there. It says
11 it's not a drug.

12 MR. STEEL: It only says it at the end of the
13 case after the decision was made. It doesn't actually say
14 that. It just says we won't address it.

15 THE COURT: Okay. Just for purposes of our
16 record, you've asked to amend for a declaratory judgment
17 that fluoride as used -- these fluoridation activities, that
18 fluoride is a drug, the fluoridated water or the fluoride is
19 a drug, both, I guess; and normally you would be able to
20 amend easily unless the amendment is futile. I believe that
21 case is on point, and so that's the basis -- I'm denying
22 your motion to amend based on the -- I can't recall -- I
23 didn't bring the case out here. All right.

24 So let's hear the arguments on the motion to
25 dismiss.

AB

1 and fluoride poisoning for infants in areas with fluoridated waters (Kailin Sec. Dec. at 3-4).
2 Even with over-the-counter drugs there is labeling that gives warnings and precautions. The
3 Cities don't provide adequate warnings to their customers because they just think of fluoride
4 as a water additive and not a drug. For example, Appendix A-30 to A-33 hereto is the annual
5 notice to water customers sent to City of Port Angeles residents in 2007 that includes no
6 warnings or precautions regarding fluoridation even though there are proven problems for
7 infants, elderly, and people with failing kidneys. Kailin Dec. at 9-10; Kailin Sec. Dec. at 2-4.
8

9 Therefore, Petitioners believe that the Honorable Judge S. Brook Taylor was wrong
10 when he said that there is not probable cause to believe that the status quo presents any
11 imminent danger to public health or safety. See Complaint at B-1. There is imminent danger
12 to infants, elderly, and people with failing kidneys. But also there is no requirement for
13 imminent danger before warrants can issue under RCW 69.41.230 and -.060 when there is a
14 violation of WAC 246-899-040(2).
15

16 **F. The Warrants In This Case "Shall" Issue When It Appears To This Court That**
17 **There Is Probable Cause To Believe That Any Legend Drug Is Being**
18 **Manufactured Or Was Offered For Sale And Is Stored Without A Needed NDA**
19 **Or ANDA**

20 There is no requirement for Notice to the Cities before this Court issues warrants to
21 the Cities similar to those in the Complaint at D-1 to D-4. RCW 69.41.230 and -.060 make
22 it mandatory for a Judge to issue warrants when it appears that there is probable cause to
23 believe that any legend drug is being manufactured or has been offered for sale in violation
24 of implementing rules of Chapter 69.41 RCW. Complaint at C-2 and C-3. Because the
25 fluoridated waters are legend drugs in interstate and intrastate commerce that are being
26

1 manufactured without the NDA or ANDA required by WAC 246-899-040(2), the Cities are
2 in violation of this WAC and the warrants should issue. See Complaint at C-1. Petitioners
3 request that this Court issue the warrants after it has reviewed this brief and the Certified
4 Complaint.

5
6 **G. The Cities' Motion To Dismiss Should Be Denied And the Cities Request For
Sanctions Should Be Denied**

7
8 **1. The Issue Raised By The Cities Must Be Restated**

9 The issue under review should be restated as follows considering that the Motion is
10 brought under CR 12.

11
12 Under any set of facts consistent with the Complaint are the
13 Cities' fluoridated waters or bulk fluoride products, drugs or
14 legend drugs?

15 **2. City of Port Angeles Is Not Useful In Determining If The Cities'
16 Fluoridated Waters Or Bulk Fluoride Products Are Drugs Or Legend
17 Drugs**

18 The Cities allege that the Supreme Court in *City of Port Angeles* made multiple
19 holdings relevant to the instant case. Motion at 3-4. However, these holdings are not
20 relevant to the instant case because the Supreme Court was just trying to establish that the
21 initiatives were "modifications of a plan already adopted by the legislative body itself, or
22 some power superior to it, indicative of an administrative act" in order to conclude that the
23 initiatives were beyond the scope of the local initiative power. *City of Port Angeles* at 596.
24 The *City of Port Angeles* Court explicitly states that it rejected the Petitioners' argument that
25 fluoride was a drug because it was not properly raised. *Id.* at 594, Note 6 ("However, the
26



RULES AND REGULATIONS

customs Form 4449 showing the name of the airport, date and time of arrival, date and time of departure and purpose of the visit. The permit shall be surrendered to the collector of customs at the port of final clearance for a foreign destination, who shall satisfy himself prior to the issuance of clearance that the aircraft received proper customs treatment while in this country. The permit shall then be returned to the collector of customs at the port of issue.

(2) A copy of the permit shall be retained by the collector at the port where issued. If within 60 days after the issuance of such permit the said collector does not receive a report of the outward clearance of the aircraft covered thereby, the matter shall be reported to the supervising customs agent for investigation.

(3) Civil aircraft registered in the United States arriving from a foreign country with passengers carried for hire or merchandise, after proper customs treatment of their cargo (passengers carried for hire or merchandise), may be allowed to proceed upon their identity being established.

This order shall become effective on the date of its publication in the FEDERAL REGISTER.

(R. S. 161, sec. 23, 39 Stat. 892, as amended, sec. 24, 43 Stat. 166; R. S. 251, secs. 624, 644, 46 Stat. 759, 761, sec. 201, 367, 58 Stat. 683, 706, sec. 7, 44 Stat. 576, as amended; 5 U. S. C. 22, 8 U. S. C. 102, 222, 19 U. S. C. 66, 1624, 1644, 42 U. S. C. 202, 270, 49 U. S. C. 177)

[SEAL] D. E. STRUBINGER,
Acting Commissioner of Customs.
JOHN S. GRAHAM,
Acting Secretary of the Treasury.
W. F. DEARING,
Acting Surgeon General,
U. S. Public Health Service.
JOHN L. THURSTON,
Acting Federal Security Administrator.
PHILIP B. PERLMAN,
Acting Attorney General.

JULY 17, 1952.

[F. R. Doc. 52-8054; Filed, July 22, 1952;
8:55 a. m.]

[T. D. 53046]

**PART 10—ARTICLES CONDITIONALLY FREE,
SUBJECT TO A REDUCED RATE, ETC.**

SUPPLIES FOR VESSELS OF WAR

The Department of State has furnished the Treasury Department an up-to-date list of countries which permit the withdrawal of supplies free of duty and tax by vessels of war of the United States while in ports of those countries. Therefore, § 10.59 (d), Customs Regulations of 1943 (19 CFR 10.59 (d)), containing a list of countries whose vessels of war shall be accorded the privilege of withdrawing supplies free of customs duties and internal-revenue tax while in ports of the United States, as provided for in section 309 (a), Tariff Act of 1930, as amended, is further amended to read as follows:

§ 10.59 *Exemption from customs duties and internal revenue tax.* * * *

(d) The privilege shall be accorded to vessels of war of the following countries:

Argentina.	Ireland.
Australia.	Mexico.
Belgium.	The Netherlands.
Brazil.	New Zealand.
Canada.	Nicaragua.
Chile.	Norway.
Colombia.	Panama.
Cuba.	The Philippines.
Denmark.	El Salvador.
The Dominican Republic.	Spain.
Ethiopia.	Sweden.
Finland.	Thailand.
France.	Turkey.
Great Britain.	Union of South Africa.
Greece.	Uruguay.
Haiti.	Venezuela.
India.	

(Sec. 5, 52 Stat. 1080; 19 U. S. C. 1309)

[SEAL] FRANK DOW,
Commissioner of Customs.

Approved: July 16, 1952.

JOHN S. GRAHAM,
Acting Secretary of the Treasury.
[F. R. Doc. 52-8025; Filed, July 22, 1952;
8:48 a. m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Federal Security Agency

**PART 3—STATEMENTS OF GENERAL POLICY
OR INTERPRETATION**

**FLUORIDATED WATER AND PROCESSED FOODS
CONTAINING FLUORIDATED WATER**

Pursuant to section 3 of the Administrative Procedure Act (60 Stat. 237, 238; 5 U. S. C. 1002), the following statement of policy is issued:

§ 3.27 *Status of fluoridated water and foods prepared with fluoridated water under the Federal Food, Drug, and Cosmetic Act.* (a) The program for fluoridation of public water supplies recommended by the Federal Security Agency, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Federal Security Agency will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug, and Cosmetic Act. Similarly, commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the fluorine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the

facts with respect to the particular case will be controlling.

(Sec. 701, 52 Stat. 1055; 21 U. S. C. 371)

Dated: July 17, 1952.

[SEAL] JOHN L. THURSTON,
Acting Administrator.

[F. R. Doc. 52-8041; Filed, July 22, 1952;
8:50 a. m.]

TITLE 26—INTERNAL REVENUE

Chapter I—Bureau of Internal Revenue, Department of the Treasury

Subchapter C—Miscellaneous Excise Taxes

[T. D. 5920; Regs. 132]

**PART 325—EXCISE AND SPECIAL TAX ON
WAGERING**

REGISTRY, RETURN AND PAYMENT OF TAX

Regulations 132 amended to require persons liable for special (occupational) wagering tax to file returns and pay tax before commencing taxable activity and to file supplemental returns advising of all agents or employees engaged to receive wagers or with respect to all persons for whom wagers are received.

On June 3, 1952, notice of proposed rule making regarding amendment of § 325.50 of Regulations 132 was published in the FEDERAL REGISTER (17 F. R. 4988). No objection to the rules proposed having been received, § 325.50 of Regulations 132 is amended to read as follows:

§ 325.50 *Registry, return, and payment of tax.* (a) No person shall engage in the business of accepting wagers subject to the 10 percent excise tax imposed by section 3295 of the Internal Revenue Code (see § 325.24) until he has filed a return on Form 11-C and paid the special tax imposed by section 3290. Likewise, no person shall engage in receiving wagers for or on behalf of any person engaged in such business until he has filed a return on Form 11-C and paid the special tax imposed by section 3290 of the Internal Revenue Code. Filing of successive applications and payment of tax by such persons are required on or before July 1 of each year thereafter during which taxable activity continues. The return, with remittance, shall be filed with the collector of internal revenue for the district in which is located the taxpayer's office or principal place of business. If such taxpayer resides in the United States, but has no office or principal place of business in the United States, the return shall be filed with the collector of internal revenue for the district in which he resides. If the taxpayer has no office, residence, or principal place of business in the United States, the return shall be filed with the Collector of Internal Revenue, Baltimore, Maryland. The collector, upon request, will furnish the taxpayer proper forms which shall be filled out and signed as indicated therein.

(b) Each return shall show the taxpayer's full name. A person doing business under an alias, style, or trade name shall give his true name, followed by his alias, style, or trade name. In the case of a partnership, association, firm,

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RULES AND REGULATIONS

Title 21—Food and Drugs
CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 9]

SUBCHAPTER C—DRUGS: GENERAL

Reorganization and Republication

The Commissioner of Food and Drugs, for the purposes of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations.

This is the ninth document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

This recodification document represents a reorganization of material remaining in Subchapter C—Drugs that has general applicability, rather than strictly human or animal use. In addition certain related sections under Parts 1 and 3 have been redesignated as part of the revised Subchapter C—Drugs: General.

The following table shows the relationship of the CFR section numbers under the former Subchapters A and C to their redesignation reflected in the new Parts 200 through 299:

Old Section	New Section	Old Section	New Section
1.100	299.5	3.21	250.102
1.101	201.6	3.22	200.101
1.101a	201.60	3.27	250.203
1.102	201.50	3.28	200.50
1.102a	201.61	3.29	201.307
1.102b	201.1	3.30	201.308
1.102c	201.61	3.35	201.303
1.102d	201.62	3.36	250.103
1.103	201.15	3.37	201.309
1.104	201.10	3.40	250.201
1.105	202.1	3.43	201.310
1.106(a)	201.5	3.44	201.311
1.106(b)	201.100	3.45	200.30
1.106(c)	201.105	3.48	250.106
1.106(d)	201.109	3.50	250.104
1.106(f)	201.110	3.52	250.107
1.106(g)	201.115	3.53	250.10
1.106(h)	201.116	3.56	201.405
1.106(i)	201.117	3.61	200.18
1.106(j)	201.119	3.62	299.4
1.106(k)	201.120	3.63	250.11
1.106(l)	201.122	3.64	250.12
1.106(m)	201.125	3.67	201.305
1.106(n)	201.127	3.71	250.100
1.106(o)	201.128	3.74	201.56
1.107	201.150	3.76	200.10
1.108(a)		3.77	290.35
& (b)	201.16	3.81	201.200
1.108(c)	290.6	3.84	201.410
1.109	290.5	3.90	250.300
1.110	290.10	3.91	250.250
1.115	200.15	3.94	250.109
3.3	201.300	3.95	250.110
3.4	201.302	3.501	200.5
3.7	250.108	3.502	201.19
3.8	250.101	3.503	201.312
3.11	201.301	3.505	201.313
3.12	201.304	3.506	200.11
3.15	201.306	3.507	201.17
3.16	200.100	3.508	201.18

Old Section	New Section	Old Section	New Section
3.509	201.314	133.11	211.58
3.510	201.315	133.12	211.110
3.512	200.31	133.13	211.60
3.513	200.7	133.14	211.62
3.514	201.55	133.15	211.115
3.515	201.160	133.100	225.1
3.516	250.105	133.101	225.20
3.518	201.161	133.102	225.30
132.1	207.3	133.103	225.10
132.2	207.20	133.104	225.42
132.3	207.21	133.105	225.102
132.4	207.22	133.106	225.40
132.5	207.25	133.107	225.80
132.6	207.30	133.108	225.58
132.7	207.31	133.109	225.110
132.8	207.35	133.110	225.115
132.9	207.37	133.200	226.1
132.10	207.26	133.201	226.20
132.11	207.39	133.202	226.30
132.31	207.40	133.203	226.10
132.51	207.65	133.204	226.42
133.1	210.3	133.205	226.102
133.2	211.1	133.206	226.40
133.3	211.20	133.207	226.80
133.4	211.30	133.208	226.58
133.5	211.10	133.209	226.110
133.6	211.42	133.210	226.115
133.7	211.101	133.300	229.25
133.8	211.40	138.1	299.3
133.9	211.55	138.2	299.20
133.10	211.80		

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user, the entire text of Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C is set forth below.

Dated: March 21, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore, 21 CFR is amended by redesignating portions of Parts 1 and 3 of Subchapter A and Parts 132, 133, and 138 of Subchapter C as Parts 200, 201, 202, 207, 210, 211, 225, 226, 229, 250, 290, and 299 of Subchapter C—Drugs: General, and republished to read as follows:

SUBCHAPTER C—DRUGS: GENERAL

Part

200—General

201—Labeling

202—Prescription Drug Advertising

207—Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

210—Current Good Manufacturing Practices in Manufacturing, Processing, Packaging, or Holding of Drugs: General

211—Current Good Manufacturing Practice for Finished Pharmaceuticals

225—Current Good Manufacturing Practice for Medicated Feeds

226—Current Good Manufacturing Practice for Medicated Premises

229—Current Good Manufacturing Practice for Certain Other Drug Products

250—Special Requirements for Specific Human Drugs

290—Controlled Drugs

299—Drugs; Official Names and Established Names

PART 200—GENERAL

Subpart A—General Provisions

- Sec. 200.5 Mailing of important information about drugs.
 - 200.7 Supplying pharmacists with indications and dosage information.
 - 200.10 Contract facilities (including consulting laboratories) utilized as extramural facilities by pharmaceutical manufacturers.
 - 200.11 Use of octadecylamine in steam lines of drug establishments.
 - 200.15 Definition of term "insulin."
 - 200.18 Use of secondhand containers for the shipment or storage of food and animal feed.
- Subpart B—Manufacturing Procedures Affecting New Drug Status**
- 200.30 Sterilization of drugs by irradiation.
 - 200.31 Timed release dosage forms.
- Subpart C—Requirements for Specific Classes or Drugs**
- 200.50 Ophthalmic preparations and dispensers.
- Subpart D—Suitability of Specific Drug Components**
- 200.100 Use of ox bile from condemned livers from slaughtered animals in the manufacture of drugs.
 - 200.101 Suprarenal glands from hog carcasses prior to final inspection.

AUTHORITY: Sec. 701, 52 Stat. 1055; 21 U.S.C. 371, unless otherwise noted.

Subpart A—General Provisions

§ 200.5 Mailing of important information about drugs.

Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care. In the public interest, such mail should be distinctive in appearance so that it will be promptly recognized and read. The Food and Drug Administration will make such mailings in accordance with the specifications set forth in this section. Manufacturers and distributors of drugs are asked to make such mailings as prescribed by this section and not to use the distinctive envelopes for ordinary mail.

(a) Use first class mail and No. 10 white envelopes.

(b) The name and address of the agency or the drug manufacturer or distributor is to appear in the upper left corner of the envelope.

(c) The following statements are to appear in the far left third of the envelope front, in the type and size indicated, centered in a rectangular space approximately 3 inches wide and 2¼ inches high with an approximately ⅜-inch-wide border in the color indicated:

(1) When the information concerns a significant hazard to health, the statement:

**IMPORTANT
 DRUG
 WARNING**

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36 point Gothic Bold type. "Drug" and "Warning" shall be in 36 point Gothic Condensed type. The rectangle's

A 12

code of federal regulations

Food and Drugs

21

PARTS 200 TO 299

Revised as of April 1, 1995

**CONTAINING
A CODIFICATION OF DOCUMENTS
OF GENERAL APPLICABILITY
AND FUTURE EFFECT**

AS OF APRIL 1, 1995

With Ancillaries

Published by
the Office of the Federal Register
National Archives and Records
Administration

as a Special Edition of
the Federal Register

A13

ing of section 503(b) of the Federal Food, Drug, and Cosmetic Act unless it is labeled with the legend "Caution—Federal law prohibits dispensing without prescription."

(e) Any drug for oral ingestion intended, represented, or advertised for the prevention or treatment of pernicious anemia or which purports to contain any substance or mixture of substances described in paragraph (d) of this section (other than diagnostic drugs containing radioactive cyanocobalamin) will be regarded as misbranded under sections 502(f)(2) and (j) of the act unless its labeling bears a statement to the effect that some patients afflicted with pernicious anemia may not respond to the orally ingested product and that there is no known way to predict which patients will respond or which patients may cease to respond to the orally ingested products. The labeling shall also bear a statement that periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.

(f) Under section 409 of the Federal Food, Drug, and Cosmetic Act, intrinsic factor and intrinsic factor concentrate are regarded as food additives. No food additive regulation nor existing extension of the effective date of section 409 of the act authorizes these additives in foods, including foods for special dietary uses. Any food containing added intrinsic factor or intrinsic factor concentrate will be regarded as adulterated within the meaning of section 402(a)(2)(C) of the act.

(g) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the act contrary to the provisions of this policy statement after the 180th day following publication of this statement in the FEDERAL REGISTER.

§ 250.203 Status of fluoridated water and foods prepared with fluoridated water.

(a) The program for fluoridation of public water supplies recommended by the Department of Health and Human Services, through the Public Health Service (Centers for Disease Control), contemplates the controlled addition

of fluorine at a level optimum for the prevention of dental caries.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Department of Health and Human Services will regard water supplies containing fluorine, within the limitations recommended by the Environmental Protection Agency, as not actionable under the Federal Food, Drug, and Cosmetic Act. Similarly, commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the fluorine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the facts with respect to the particular case will be controlling.

[40 FR 14033, Mar. 27, 1975, as amended at 48 FR 11426, Mar. 18, 1983]

Subpart D—Requirements for Drugs and Cosmetics

§ 250.250 Hexachlorophene, as a component of drug and cosmetic products

(a) *Antibacterial component.* The use of hexachlorophene as an antibacterial component in drug and cosmetic products has expanded widely in recent years. It is used in such products because of its bacteriostatic action against gram-positive organisms, especially against strains of staphylococcus; however, hexachlorophene offers no protection against gram-negative infections. In addition, the antibacterial activity depends largely on repeated use. A notice published in the FEDERAL REGISTER of April 4, 1972 (37 FR 6775), invited data on OTC antimicrobial ingredients, including hexachlorophene, for review by an OTC Drug Advisory Review Panel to be convened under the procedures set forth in the FEDERAL REGISTER of May 11, 1972

List of substances	Limitations
Monochlorobenzene Monochlorobenzene.	Not to exceed 500 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
N-methyl-2-pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in paragraph (a)(2) of this section.

* * * * *

Dated: May 17, 1996.
 Fred R. Shank,
 Director, Center for Food Safety and Applied Nutrition.
 [FR Doc. 96-14697 Filed 6-10-96; 8:45 am]
 BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Parts 200, 250, and 310

[Docket No. 95N-0310]

Revocation of Obsolete Regulations

AGENCY: Food and Drug Administration, HHS.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations that are obsolete or are no longer necessary to achieve public health goals. These regulations were among those identified for revocation in a page-by-page review conducted in response to the Administration's "Reinventing Government" initiative, which seeks to streamline government to ease the burden on regulated industry and consumers.

EFFECTIVE DATE: July 11, 1996.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 13, 1995 (60 FR 53480), FDA published a proposed rule to revoke certain regulations. This was done in response to the President's order to all Federal agencies to conduct a page-by-page review of all their regulations and to

"eliminate or revise those that are outdated or otherwise in need of reform." The proposed rule contained a section-by-section analysis of all the regulations (21 CFR parts 100, 101, et al.) that FDA intended to revoke. This final rule pertains only to those regulations (21 CFR parts 200, 250, and 310) pertaining exclusively to the Center for Drug Evaluation and Research. No comments were received in response to the proposal to revoke these regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule, which is the revocation of certain regulations that are obsolete or are no longer necessary, is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is the revocation of certain regulations that are obsolete or are no longer necessary, the agency is not aware of any adverse impact this final rule will have on any small entities, and the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 200, 250, and 310 are amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

2. Sections 200.100 and 200.101 are removed and the heading for subpart D is reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

3. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.104 [Removed]

4. Section 250.104 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act* is removed.

§ 250.203 [Removed]

5. Section 250.203 *Status of fluoridated water and foods prepared with fluoridated water* is removed.

PART 310—NEW DRUGS

6. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512-516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b-360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354-360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b-263n).

§ 310.101 [Removed]

7. Section 310.101 *FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy* is removed.

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ENVIRONMENTAL PROTECTION AGENCY

[OW-FRL-3410-1]

Drinking Water Technical Assistance; Termination of the Federal Drinking Water Additives Program**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: The Environmental Protection Agency (EPA), Office of Drinking Water (ODW), has operated an advisory program that gives technical assistance to concerned parties on the use of drinking water additives. On May 17, 1984, EPA proposed to terminate major elements of this Federal program and to assist in the establishment of a private-sector program which would offer assistance in evaluating drinking water additives. 49 FR 21004. EPA solicited proposals from qualified nongovernmental, nonprofit organizations for assistance under a cooperative agreement to establish a credible and efficient program in the private sector.

On September 17, 1985, EPA selected a consortium consisting of the National Sanitation Foundation (NSF), the American Water Works Association Research Foundation (AWWARF), the Conference of State Health and Environmental Managers (COSHEM), and the Association of State Drinking Water Administrators (ASDWA) to receive funds under a cooperative agreement to develop the private-sector program. EPA believes that the NSF-led program has proceeded satisfactorily. NSF Standard 60, covering many direct additives, was adopted on December 7, 1987; and NSF Standard 61, covering indirect additives, was adopted on June 3, 1988. Other standards are forthcoming. The NSF-led program has begun offering testing, certification, and listing services, as described in 49 FR 21004, for certain classes of products covered by these standards. Accordingly, as the NSF-led program becomes operational, EPA will phase out its activities in this area, as described in this notice.

DATE: Any written comments on implementing this notice should be submitted to the address below by September 6, 1988.

ADDRESSES: Submit comments to: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. A copy of all comments will be available for review

during normal business hours at the U.S. Environmental Protection Agency, Criteria and Standards Division, Science and Technology Branch, Room 931ET, 401 M Street, SW., Washington, DC 20460. For further information on the NSF-led private-sector program, including standards development and testing, certification, and listing services, contact: Director, Drinking Water Additives Program, National Sanitation Foundation, P.O. Box 1468, Ann Arbor, MI 48106; or call (313) 769-8010. For information on alternative testing, certification, and listing programs, contact individual State regulatory authorities or the American Water Works Association, Technical and Professional Department, 6666 Quincy Avenue, Denver CO, 80235, or call (303) 794-7711. For information on the directory of products certified as meeting the criteria in a NSF standard, contact the American Water Works Association Research Foundation, 6666 Quincy Avenue, Denver CO, 80235, or call (303) 794-7711.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, or call (202) 382-2022.

I. Introduction

The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*) provides for enhancement of the safety of public drinking water supplies through the establishment and enforcement of national drinking water regulations. The Environmental Protection Agency (EPA) has the primary responsibility for establishing the regulations, and the States have the primary responsibility for enforcing such regulations. The regulations control contaminants in drinking water which may have any adverse effect on public health. Section 1412, 42 U.S.C. 300g-1. The regulations include maximum contaminant levels (MCLs) or treatment techniques and monitoring requirements for these contaminants. Sections 1401 and 1412; 42 U.S.C. 300f and 300g-1. EPA also promulgates monitoring requirements for unregulated contaminants. Section 1445; 42 U.S.C. 300j-4. In addition, EPA has broad authorities to provide technical assistance and financial assistance (e.g., grants, cooperative agreements) to States and to conduct research. Sections 1442, 1443, 1444; 42 U.S.C. 300j-1, 300j-2, 300j-3.

The Agency has established MCLs for a number of harmful contaminants that occur naturally or pollute public

drinking water supplies. In addition to such contaminants, there is a possibility that drinking water supplies may be contaminated by compounds "added" to drinking water, either directly or indirectly, in the course of treatment and transport of drinking water. Public water systems use a broad range of chemical products to treat water supplies and to maintain storage and distribution systems. For instance, systems may directly add chemicals such as chlorine, alum, lime, and coagulant aids in the process of treating water to make it suitable for public consumption. These are known as "direct additives." In addition, as a necessary function of maintaining a public water system, storage and distribution systems (including pipes, tanks, and other equipment) may be fabricated from or painted, coated, or treated with products which may leach into or otherwise enter the water. These products are known as "indirect additives." Except to the extent that direct or indirect additives consist of ingredients or contain contaminants for which EPA has promulgated MCLs, EPA does not currently regulate the levels of additives in drinking water.

In 1979, EPA executed a Memorandum of Understanding (MOU) with the U.S. Food and Drug Administration (FDA) to establish and clarify areas of authorities with respect to control of additives in drinking water. 44 FR 42775, July 20, 1979. FDA is authorized to regulate "food additives" pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA). (21 U.S.C. 301 *et seq.*) Both agencies acknowledged in the MOU that "passage of the SDWA in 1974 repealed FDA's authority under the FFDCA over water used for drinking water purposes." The MOU stated that FDA would continue to have authority for taking regulatory action under the FFDCA to control additives in bottled drinking water and in water used in food and for food processing. The MOU went on to say that EPA had authority to control additives in public drinking water supplies.

While the SDWA does not require EPA to control the use of specific additives in drinking water, EPA has provided technical assistance to States and public water systems on the use of additives through the issuance of advisory opinions on the acceptability of many additive products. EPA has provided this technical assistance pursuant to its discretionary authority in section 1442(b)(1) to "collect and make available information pertaining to research, investigations and demonstrations with respect to

providing a dependable safe supply of drinking water together with appropriate recommendations in connection therewith." EPA has additional authorities under the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601 *et seq.*) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*) that could be used to control additives in drinking water. TSCA authorizes EPA to regulate a new chemical substance before it is manufactured or any existing chemical substance before it is manufactured or processed for a use that EPA has determined to be a "significant new use." Although an additive product might come within the jurisdiction of TSCA, EPA has never invoked this authority. EPA has used its authority under FIFRA to control the use of pesticides, disinfectants, and certain other additives. For a more complete discussion of these authorities, see the MOU. 44 FR 42776.

In 1980, EPA declared a moratorium on the issuance of new advisory opinions on additives pending a review of past advisory opinions and the establishment of uniform test protocols and decision criteria. However, between 1980 and 1984, EPA continued to issue advisory opinions in cases where the new additive products were virtually identical to products previously reviewed. Resource constraints and the need to implement mandatory provisions of the SDWA precluded the Agency from implementing the comprehensive program originally envisioned for the issuance of additives advisory opinions. Thus, the Agency was not able to review the technical data supporting previous submissions (approximately 2,300 products from 525 manufacturers) nor was it able to develop test protocols or decision criteria for the consistent evaluation of new products. The result has been long delays in processing manufacturer petitions, inability to review and accept completely new products, and acceptance of products simply because they were virtually identical to older products. Hence, few products have been thoroughly evaluated for the safety of their formulations based on the latest scientific information.

Recognizing the need for continuing technical assistance in evaluating additive products and for providing advice to States and public water systems on the toxicological aspects of additive products, the Agency proposed to terminate its attempts to institute a formal advisory program, and to solicit proposals from nongovernmental, nonprofit organizations to establish such

a program in the private sector. The Agency believed that the proposal to assist in the establishment of a private-sector program was consistent with, and would best serve the goals of, the SDWA.

On May 17, 1984, EPA formally announced its intention to transfer the program to the private sector, which would function as to many other voluntary product-standard programs. 49 FR 21004. This was accomplished by requesting proposals from qualified organizations or consortia of organizations for the competitive award of a cooperative agreement designed to provide incentive for the establishment of a private-sector program. The 1984 notice stated that:

- EPA expected the activity to be self-supporting.
- EPA would maintain an active interest in the development of the program, without assuming responsibility for or directing its approach.
- EPA would continue to establish regulations under the SDWA, FIFRA, and/or TSCA, as needed, for chemicals in treated, distributed drinking water that may originate as additives.
- Establishment of such a program would be consistent with the Administration's initiatives in the area of regulatory reform and offered an opportunity for an innovative alternative to regulation.

The May 1984 notice requested public comments on the proposal and solicited applications from qualified nongovernmental, nonprofit organizations for partial funding of the developmental phase of the program under a cooperative agreement. The response to the solicitation for comments indicated strong public support for the proposed approach. EPA received 106 public comments on the proposal. All but six supported this "third-party" approach. However, despite the Agency's open competition, EPA received only one application for financial assistance. The applicant was a consortium, led by the National Sanitation Foundation, which included the American Water Works Association Research Foundation, the Conference of State Health and Environmental Managers, and the Association of State Drinking Water Administrators. This single proposal met all of the basic criteria articulated in the May 1984 notice. Furthermore, EPA believed that the single applicant was very likely to succeed, because it represented an organization experienced in private-sector consensus standard-setting, State regulators, and water utilities.

EPA awarded the cooperative agreement to the NSF consortium on September 17, 1985, and committed funding of \$185,000 to NSF over a three-year period. The non-Federal (consortium and participating industry) contribution during the first three years of the program was projected to be approximately \$1.4 million.

The NSF program has the following major objectives:

- To develop systematic, consistent, and comprehensive voluntary consensus standards for public health safety evaluation of all products (previously EPA-accepted as well as new) intended for use in drinking water systems.
- To obtain broad-based participation in the standard-setting program from industry, States, and utilities.
- To provide for regular periodic review, update, and revision of the standards.
- To undertake needed research, testing, evaluation, and inspections and to provide the followup necessary to maintain the program.
- To establish a separate program for testing, evaluation, certification, and listing of additive products.
- To widely disseminate information about the program, and to make information about conforming products available to users.
- To maintain the confidentiality of all proprietary information.
- To fully establish the third-party program on a self-supporting basis.

NSF's established standard-setting process utilizes a tiered structure. Each standard is drafted by a task group and then presented to a Joint Committee, which includes 12 industry, 12 user, and 12 regulatory members. Following successful Joint Committee balloting, standards are reviewed by the Council of Public Health Consultants, which is a high level advisory group consisting of technical and policy experts from regulatory agencies and academia.

NSF has established task groups to develop standards for the product categories listed below. Each task group includes a member representing the regulatory agencies and a member representing the utilities. All manufacturers expressing interest in a particular product task group may participate as members of that group. Therefore, task group membership is predominately manufacturers. In addition, a group of health effects consultants is addressing the toxicological and risk considerations for various product categories. NSF's role in the standard-setting process is administrative, that is, to bring together experts from government, industry,

utilities, users, and other relevant groups so that a standard which reflects a consensus of these interests can be developed. In addition, NSF staff provide technical leadership and laboratory support. Product categories and corresponding task groups are:

- Protective Materials.
- Chemicals for Corrosion and Scale Control, Softening, Precipitation, Sequestering, and pH Adjustment.

• Coagulation and Flocculation Chemicals.

• Miscellaneous Treatment Chemicals.

- Joining and Sealing materials.
- Process Media.
- Pipes and Related Products.
- Disinfection and Oxidation Chemicals.

• Mechanical Devices.

All of the task groups have made satisfactory progress during the term of the cooperative agreement. In addition, the health effects consultants have endorsed the bases of the standards. Standards have been drafted for all product categories, and final standards were published and implemented as follows:

Standard 60, December 1987

- Chemicals for Corrosion and Scale Control, Softening, Precipitation, Sequestering, and pH Adjustment.

• Disinfection and Oxidation Chemicals.

• Miscellaneous Treatment Chemicals (selected).

Standard 61, June 1988

- Process Media.
- Development of the remaining standards is on schedule, and publication and implementation are expected on the following schedule:

Standards 60 and 61, expected October 1988

- Protective Materials.
- Coagulation and Flocculation Chemicals.
- Miscellaneous Treatment Chemicals (additional).
- Joining and Sealing Materials.
- Pipes and Related Products.
- Mechanical Devices.

EPA believes that the NSF program is successfully pursuing all of its objectives. Furthermore, the program is strongly supported by user and regulatory sectors. AWWARF, COSHEM, ASDWA, the Great Lakes Upper Mississippi River Board, the American Water Works Association (AWWA) (including the Utilities and Standards Councils and the Regulatory Agencies Division), and the Association of Metropolitan Water Agencies, among

others, have voiced strong support for the third-party program. The AWWA recently joined the NSF-led consortium and urged EPA to support national uniform accreditation of certifying entities for additives products. To date, more than 60 manufacturers are full participants in the standard-setting program.

The cooperative agreement between EPA and the consortium requires NSF to establish both a standard-setting program and a service for testing, certification, and listing. These are completely separate activities. EPA's intent is to support the development of a widely accepted uniform standard for each category of products while encouraging the development of competing sources for testing, certification, and listing. The cooperative agreement assures that at least one sound and reliable product-evaluation service will be available to manufacturers, i.e., the consortium. However, the consortium's standards will allow for entities other than NSF to be evaluators of products.

EPA recognizes the authority and responsibility of the individual States to determine the acceptability of drinking water additives. Hence, it is up to the States and utilities to determine the suitability of any "third-party" certification. AWWARF will maintain a directory of products approved by all organizations claiming to conduct evaluations under Standards 60 and 61. However, AWWARF will not judge the competence or reliability of these organizations.

II. Announcement of Phase-Down of EPA's Additives Program

During the developmental phase of the NSF consortium's program, EPA has continued to review products and process requests for advisory opinions on a limited basis. The May 1984 notice stated that, "EPA does not intend to develop further interim administrative procedures, testing protocols or decision criteria for future evaluation of additive products. The use of existing informal criteria will continue until a third-party or alternative program is operational * * *. EPA may not be able to process all requests for opinions on additive products before the establishment of a cooperative agreement with a third party. The large volume of currently pending requests makes it unlikely that additional requests will be completely processed by that date." Likewise, EPA, in its acknowledgment letters to manufacturers requesting opinions on new products, explains that the Agency is, " * * * making a concerted effort to process petitions as quickly as possible.

However, EPA may not be able to process your request for an opinion on an additive product before the establishment of an alternative program as described in the **Federal Register**, Vol. 49, No. 97, 21003-8, May 17, 1984." Product reviews and issuance of advisory opinions have been limited to:

- Products composed entirely of other products which EPA had previously determined to be acceptable;

- Products composed entirely of ingredients which have been determined to be acceptable by EPA or the FDA, or other Federal agencies, for addition to potable water or aqueous foods;

- Products composed entirely of ingredients listed in the "Water Chemicals Codex," National Academy of Sciences, November 1982, and in the "Water Chemicals Codex: Supplementary Recommendations for Direct Additives," National Academy of Sciences, 1984;

- Certain other products of particular interest to EPA or to other Federal agencies; and

- Products which, if effectively excluded from the marketplace by lack of approval, might jeopardize public health or safety.

Continued processing of petitions during the development of the private-sector program minimized disruption of the marketplace from the viewpoint of manufacturers whose business depended in part on EPA acceptance of products, users who required water treatment products for the production of safe drinking water, and State officials who rely on the advice of EPA.

EPA believes that NSF is moving expeditiously and on schedule toward the full establishment of a third-party program covering products intended for use in drinking water systems. Priorities for standards development and implementation of a testing, certification, and listing program for various product categories have been based upon need, interest, complexity, and availability of information for developing standards. Direct drinking water additives were assigned high priority for the following reasons: (1) Use of direct additives is widespread in drinking water systems, so there are large population exposures to these chemicals; (2) as direct additives to drinking water, they present greater potential for water contamination than indirect mechanisms (e.g., migration from protective paints in pipes and storage tanks); and (3) the National Academy of Sciences' *Water Chemicals Codex* provided a good starting point for development of standards.

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As originally planned, EPA is beginning to phase out the Agency's additives evaluation program. Thus, EPA will not accept new petitions or requests for advisory opinions after the date of this notice. While EPA will continue to process requests which are pending and those received on or before July 7, 1988, petition evaluations not completed by October 4, 1988, will be returned to the submitter. After that date, EPA will no longer evaluate additive products.

Petitions which are completely evaluated by October 5, 1988, will be added to the quarterly list of acceptable products published shortly after that date. That quarterly list will be the last such list issued by EPA. On April 7, 1990, EPA will withdraw its list of acceptable products, and the list and the advisories on these additives will expire. This means that: (1) The various lists published by EPA under the titles *Report on Acceptable Drinking Water Additives*, *Report on Coagulant Aids for Water Treatment*, *Report on Concrete Coatings/Admixture for Water Treatment*, *Report on Detergents, Sanitizers and Joint Lubricants for Water Treatment*, *Report on Evaporative Suppressants for Water Treatment*, *Report on Liners/Grouts/Hoses and Tubings for Water Treatment*, *Report on Miscellaneous Chemicals for Water Treatment*, *Report on Protective Paints/Coatings for Water Treatment*, and any and all other lists of drinking water products issued by EPA or its predecessor agencies regarding drinking water additives will be invalid after April 7, 1990; and (2) advisory opinions on drinking water additives issued by EPA and predecessor agencies will be invalid after that date.

EPA believes that, while in the past every effort has been made to provide the best possible evaluations, all products should be evaluated against carefully developed and considered

nationally uniform standards. Many of the currently listed products were evaluated and accepted up to 20 years ago and have not been reevaluated since that time. Numerous products have been accepted because they were virtually identical to or were repackagings of older products. The result is that few products have been completely evaluated for the safety of their original or current formulations vis-a-vis the latest toxicological, chemical, and engineering information. A uniform evaluation of all products, old and new, will result in consistent quality of products, and will assure fair and equitable treatment to all manufacturers and distributors.

Henceforth, parties desiring to have existing or new products evaluated against the NSF standards should contact NSF or other organizations offering such evaluations. To contact NSF about the drinking water additives program write to: David Gregorka, National Sanitation Foundation, P.O. Box 1468, Ann Arbor, MI 48106, or call (313) 769-8010. Information on alternatives to NSF evaluation may be obtained by contacting State regulatory agencies or the AWWA, Technical and Professional Department, 6666 Quincy Avenue, Denver Co, 80235, or call (303) 794-7711, which is addressing certifier accreditation.

EPA believes that the 21 months between today and the expiration date of EPA's last list is sufficient time for manufacturers to submit their products to NSF or other certification entities for evaluation. The first NSF list will be published prior to April 7, 1990, thereby preventing any disruption in the marketplace. Furthermore, NSF had indicated that it will consider current EPA and other regulatory evaluations when evaluating products in order to ensure a smooth transition. States may choose to rely on the last EPA quarterly list of products until their individual

programs for accepting private-sector certification are fully implemented.

Parties desiring to market drinking water additive products are reminded that the individual States have the authority to regulate the sale and/or use of specific products as they see fit. Thus, reliance upon a particular standard or organization to certify that a product complies with a particular standard must be acceptable to the State in which the supplier wishes to do business.

Discontinuation of the additives program at EPA does not relieve the Agency of its statutory responsibilities. If contamination resulting from third-party sanctioned products occurs or seems likely, EPA will address that issue with appropriate drinking water regulations or other actions authorized under the SDWA. EPA is a permanent member of the NSF program Steering Committee, and senior EPA staff and management will continue to participate in this and other programs designed to assure that high-quality products are employed in the treatment of public drinking water. Also, the Agency will continue to sponsor research on contaminants introduced in public water supplies during water treatment, storage, and distribution.

III. Comments

Although this notice does not include a proposed or final regulation, EPA welcomes comments and suggestions that would assist the Agency in implementing the additives program phasedown. Please address all comments and suggestions to: Mr. Arthur H. Perler, Chief, Science and Technology Branch, Office of Drinking Water (WH-550D), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Date: June 16, 1988.

William Whittington,

Acting Assistant Administrator for Water.

[FR Doc. 88-15232 Filed 7-6-88; 8:45 am]

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§ 321. Definitions; Generally.

Archive

United States Statutes

Title 21. Food and Drugs

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter II. DEFINITIONS

Current through P.L. 111-290

§ 321. Definitions; Generally

For the purposes of this chapter-

- (a)
 - (1) The term "State", except as used in the last sentence of section **372 (a)** of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.
 - (2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.
- (b) The term "interstate commerce" means
 - (1) commerce between any State or Territory and any place outside thereof, and
 - (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.
- (c) The term "Department" means Department of Health and Human Services.
- (d) The term "Secretary" means the Secretary of Health and Human Services.
- (e) The term "person" includes individual, partnership, corporation, and association.
- (f) The term "food" means
 - (1) articles used for food or drink for man or other animals,
 - (2) chewing gum, and

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- (3) articles used for components of any such article.
- (g) (1) The term "drug" means
- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
 - (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
 - (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
 - (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections **343 (r)(1)(B)** and **343 (r)(3)** of this title or sections **343 (r)(1)(B)** and **343 (r)(5)(D)** of this title, is made in accordance with the requirements of section **343 (r)** of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section **343 (r)(6)** of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.
- (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.
- (h) The term "device" (except when used in paragraph (n) of this section and in sections **331 (i)**, **343 (f)**, **352 (c)**, and **362 (c)** of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-
- (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended

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- (dd) For purposes of sections **335a** and **335b** of this title, the term "drug product" means a drug subject to regulation under section **355**, **360b**, or **382** of this title or under section **262** of title 42.
- (ee) The term "Commissioner" means the Commissioner of Food and Drugs.
- (ff) The term "dietary supplement"-
- (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);
 - (2) means a product that-
 - (A)
 - (i) is intended for ingestion in a form described in section **350 (c)(1)(B)(i)** of this title; or
 - (ii) complies with section **350 (c)(1)(B)(ii)** of this title;
 - (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
 - (C) is labeled as a dietary supplement; and
 - (3) does-
 - (A) include an article that is approved as a new drug under section **355** of this title or licensed as a biologic under section **262** of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section **342 (f)** of

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this title; and

- (B) not include-
- (i) an article that is approved as a new drug under section **355** of this title, certified as an antibiotic under section **357** of this title, or licensed as a biologic under section **262** of title 42, or
 - (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

- (gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.
- (hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.
- (ii) The term "compounded positron emission tomography drug"-
- (1) means a drug that-
 - (A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and
 - (B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and
 - (2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

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drug products rulemaking and the OTC topical antimicrobial drug products rulemaking, the FDA agreed that a product that contains antimicrobial ingredients to reduce microbial flora solely for the purpose of cleansing or reducing odor is a cosmetic and not a drug and that such cosmetic uses are outside the scope of OTC drug monographs. Concluding that the Oral Cavity Panel's recommendations are without legal foundation and are contrary to the provisions of the act and the legal precedents established for more than 40 years, the comments requested that FDA reject the Panel's recommendations and adhere to the traditional drug/cosmetic distinctions.

One comment stated that the Oral Cavity Panel appeared to base its proposal to delete all cosmetic indications for antimicrobial mouthwash products on the finding that topical antimicrobials as a class are unsafe and ineffective. Asserting that action to be contrary to the substantial scientific evidence presented to that Panel and to the Advisory Review Panels on OTC Topical Antimicrobial Drug Products (the Antimicrobial I and II Panels), the comment stated that antimicrobial ingredients, used appropriately, are no less safe than other ingredients commonly used as cosmetics. A reply comment added that there are extensive scientific data demonstrating the effectiveness of an antimicrobial mouthwash in suppressing mouth odor.

Another reply comment agreed with the Panel that cosmetic claims are not acceptable as "indications" for the OTC oral health care drug products rulemaking insofar as cosmetic claims are not drug indications. However, the reply comment stated that this should not preclude truthful and nonmisleading information about the cosmetic usefulness in the product's labeling and mentioned antidandruff shampoos and anticaries toothpastes as two examples of OTC products with both drug and cosmetic claims. The reply comment argued that dual claims should be permitted for an OTC oral health care drug product, e.g., that it refreshes or deodorizes the mouth (a cosmetic claim) and aids in the temporary relief of discomfort due to occasional sore throat or sore mouth (a drug claim), just as such dual claims are permitted for antidandruff shampoos, which are represented to clean hair (a cosmetic claim) and to prevent dandruff (a drug claim), and for anticaries toothpastes, which are represented to clean teeth and to prevent tooth decay.

The comments requested that the agency recognize the following phrases

as cosmetic claims for OTC oral health care products and, therefore, consider them as outside the scope of the OTC drug review: "Kills germs that cause bad breath," "mouth refreshment," "clean feeling," "control of mouth odor," "control of bad breath," "an aid to the daily care of the mouth," and "causing the mouth to feel clean." Two comments argued that terms such as "antimicrobial," "antiseptic," "kills germs," "kills germs by millions on contact," "antibacterial," and other synonymous phrases can be properly used to describe cosmetic functions, i.e., cleansing or refreshing and deodorizing, without creating drug connotations. The comments stated that when used in connection with oral hygiene and deodorizing representations, such claims are cosmetic claims because the context in which they appear connotes cosmetic purposes only. These comments concluded that mouthwashes, rinses, and gargles labeled solely with traditional cosmetic claims for cleansing, refreshing, or deodorizing the mouth or breath are subject to regulation only as cosmetics and not as drugs.

The Oral Cavity Panel stated that claims for the suppression of mouth odor in the labeling of OTC antiseptic health care products are drug claims because they are linked to a drug action, i.e., antimicrobial activity (47 FR 22760 at 22844). Concluding that such claims " * * * indicate that a product is used for cosmetic purposes but imply that the product exerts a therapeutic effect" (47 FR 22857), the Panel classified claims for the suppression of mouth odor as well as claims for the cleansing or freshening of the mouth in Category II.

The act provides the statutory definitions that differentiate a drug from a cosmetic. A "drug" is defined as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body * * *," (21 U.S.C. 321(g)(1)(B) and 321(g)(1)(C)). A "cosmetic," on the other hand, is defined as an article intended to be " * * * applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * *" (21 U.S.C. 321(i)(1)). The agency agrees with the comments that the intended use of a product is the primary determining factor as to whether it is a drug, a cosmetic, or both. This intended use may be inferred from the product's labeling, promotional material, advertising, and any other relevant factor. (See, e.g., *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).)

In determining whether a product is a drug or a cosmetic, the intended use may be established from the type and amount of ingredient(s) present, as well as the product's labeling. For example, in some instances, the mere presence of certain therapeutically active ingredients could make a product a drug even in the absence of drug claims. In these cases, the intended use would be implied because of the known or recognized drug effects of the ingredient (e.g., fluoride in a dentifrice). However, in other instances, the presence of an ingredient (e.g., an antimicrobial), in and of itself, does not make a product a drug when no drug claim is made.

The agency does not agree with the Panel that claims for the suppression of mouth odor in the labeling of an oral product containing an antiseptic ingredient necessarily makes that product a drug. Oral products that contain antiseptic ingredients are considered "cosmetics," and not "drugs," if only deodorant (or other cosmetic) claims are made for the products. The agency stated in the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648) that the mere presence of an antimicrobial ingredient in a product labeled for deodorant use, with the ingredient identified only in the ingredient list and no reference to its antimicrobial properties stated elsewhere in the labeling, would not cause the product to be considered a drug. Claims such as "mouth refreshment," "clean feeling," "control of mouth odor," "control of bad breath," and "for causing the mouth to feel clean" are considered cosmetic claims in accordance with section 201(i) of the act and are not included in this tentative final monograph.

However, any broader claims that represent or suggest a therapeutic use for the product would subject it to regulation as a drug. For example, the agency considers the phrase "an aid to daily care of the mouth" to be a drug claim because it implies that the product exerts a therapeutic benefit. The agency also considers terms such as "antibacterial," "antimicrobial," "antiseptic," or "kills germs" in the labeling of oral products to imply that the product will have a therapeutic effect. The agency concludes that such statements would constitute a drug claim for the product because consumers would perceive the intended effect to be achieved by a drug action. Likewise, any of the cosmetic statements mentioned above could become part of a drug claim if additional statements are included. For example, cosmetic claims such as



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Regulatory Information

Significant Amendments to the FD&C Act

Significant Amendments to the FD&C Act:

Since 1980, listed chronologically; date shown is when the Public Law was approved. "Summary" indicates link to a summary of the law; other links are to full text. Provisions of these Public Laws are incorporated into the FD&C Act.

- [Infant Formula Act of 1980 \(summary\)](#)¹
Public Law (PL) 96-359 (Oct. 26, 1980)
- [Orphan Drug Act](#)²
PL 97-414 (Jan. 4, 1983)
- [Drug Price Competition and Patent Term Restoration Act of 1984 \(summary\)](#)³
PL 98-417 (Sept. 24, 1984)
- [Prescription Drug Marketing Act of 1987](#)⁴
PL 100-293 (Apr. 22, 1988)
- [Generic Animal Drug and Patent Term Restoration Act of 1988 \(summary\)](#)⁵
PL 100-670 (Nov. 16, 1988)
- [Nutrition Labeling and Education Act of 1990 \(summary\)](#)⁶
PL 101-535 (Nov. 8, 1990)
- [Safe Medical Devices Act of 1990 \(summary\)](#)⁷
PL 101-629 (Nov. 28, 1990)
- [Medical Device Amendments of 1992 \(summary\)](#)⁸
PL 102-300 (June 16, 1992)
- [Prescription Drug Amendments of 1992; Prescription Drug User Fee Act of 1992](#)⁹
PL 102-571 (Oct. 29, 1992)
- [Animal Medicinal Drug Use Clarification Act \(AMDUCA\) of 1994](#)¹⁰
PL 103-396 (Oct. 22, 1994)
- [Dietary Supplement Health and Education Act of 1994](#)¹¹
PL 103-417 (Oct. 25, 1994)
- [FDA Export Reform and Enhancement Act of 1996](#)¹²
PL 104-134 (April 26, 1996)
- [Food Quality Protection Act of 1996](#)¹³
PL 104-170 (Aug. 3, 1996)
- [Animal Drug Availability Act of 1996](#)¹⁴
PL 104-250 (Oct. 9, 1996)
- [Food and Drug Administration Modernization Act \(FDAMA\) of 1997](#)¹⁵
PL 105-115 (Nov. 21, 1997)
- [Best Pharmaceuticals for Children Act](#)¹⁶
PL 107-109 (Jan. 4, 2002)
- [Medical Device User Fee and Modernization Act \(MDUFMA\) of 2002](#)¹⁷
PL 107-250 (Oct. 26, 2002)
- [Animal Drug User Fee Act of 2003](#)¹⁸
PL 108-130 (Nov. 18, 2003)
- [Pediatric Research Equity Act of 2003](#)¹⁹
PL 108-155 (Dec. 3, 2003)
- [Minor Use and Minor Species Animal Health Act of 2004](#)²⁰
PL 108-282 (Aug. 2, 2004)
- [Dietary Supplement and Nonprescription Drug Consumer Protection Act](#)²¹
PL 109-462 (Dec. 22, 2006)
- [Food and Drug Administration Amendments Act \(FDAAA\) of 2007](#)²²
PL 110-85 (Sept. 27, 2007)
- [Family Smoking Prevention and Tobacco Control Act \(Public Law 111-31\)](#)²³
PL 111-31 (June 22, 2009)
- [FDA Food Safety Modernization Act](#)²⁴
PL 111-353 (Jan. 4, 2011)

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2. </RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/OrphanDrugAct/default.htm>

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3. <http://thomas.loc.gov/cgi-bin/bdquery/z?d098:SN01538:@@D&summ2=m&|TOM:/bss/d098query.html>
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RCW 43.20.050

Powers and duties of state board of health — Rule making — Delegation of authority — Enforcement of rules.

(1) The state board of health shall provide a forum for the development of public health policy in Washington state. It is authorized to recommend to the secretary means for obtaining appropriate citizen and professional involvement in all public health policy formulation and other matters related to the powers and duties of the department. It is further empowered to hold hearings and explore ways to improve the health status of the citizenry.

In fulfilling its responsibilities under this subsection, the state board may create ad hoc committees or other such committees of limited duration as necessary.

(2) In order to protect public health, the state board of health shall:

(a) Adopt rules for group A public water systems, as defined in RCW 70.119A.020, necessary to assure safe and reliable public drinking water and to protect the public health. Such rules shall establish requirements regarding:

(i) The design and construction of public water system facilities, including proper sizing of pipes and storage for the number and type of customers;

(ii) Drinking water quality standards, monitoring requirements, and laboratory certification requirements;

(iii) Public water system management and reporting requirements;

(iv) Public water system planning and emergency response requirements;

(v) Public water system operation and maintenance requirements;

(vi) Water quality, reliability, and management of existing but inadequate public water systems; and

(vii) Quality standards for the source or supply, or both source and supply, of water for bottled water plants;

(b) Adopt rules as necessary for group B public water systems, as defined in RCW 70.119A.020. The rules shall, at a minimum, establish requirements regarding the initial design and construction of a public water system. The state board of health rules may waive some or all requirements for group B public water systems with fewer than five connections;

(c) Adopt rules and standards for prevention, control, and abatement of health hazards and nuisances related to the disposal of human and animal excreta and animal remains;

(d) Adopt rules controlling public health related to environmental conditions including but not limited to heating, lighting, ventilation, sanitary facilities, and cleanliness in public facilities including but not limited to food service establishments, schools, recreational facilities, and transient accommodations;

(e) Adopt rules for the imposition and use of isolation and quarantine;

(f) Adopt rules for the prevention and control of infectious and noninfectious diseases, including food and vector borne illness, and rules governing the receipt and conveyance of remains of deceased persons, and such other sanitary matters as may best be controlled by universal rule; and

(g) Adopt rules for accessing existing databases for the purposes of performing health related research.

(3) The state board shall adopt rules for the design, construction, installation, operation, and maintenance of those on-site sewage systems with design flows of less than three thousand five hundred gallons per day.

(4) The state board may delegate any of its rule-adopting authority to the secretary and rescind such delegated authority.

(5) All local boards of health, health authorities and officials, officers of state institutions, police officers, sheriffs, constables, and all other officers and employees of the state, or any county, city, or township thereof, shall enforce all rules adopted by the state board of health. In the event of failure or refusal on the part of any member of such boards or any other official or person mentioned in this section to so act, he or she shall be subject to a fine of not less than fifty dollars, upon first conviction, and not less than one hundred dollars upon second conviction.

(6) The state board may advise the secretary on health policy issues pertaining to the department of health and the state.

[2011 c 27 § 1; 2009 c 495 § 1; 2007 c 343 § 11; 1993 c 492 § 489; 1992 c 34 § 4. Prior: 1989 1st ex.s. c 9 § 210; 1989 c 207 § 1; 1985 c 213 § 1; 1979 c 141 § 49; 1967 ex.s. c 102 § 9; 1965 c 8 § 43.20.050; prior: (i) 1901 c 116 § 1; 1891 c 98 § 2; RRS § 6001. (ii) 1921 c 7 § 58; RRS § 10816.]

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Notes:

Effective date -- 2009 c 495: "Except for section 9 of this act, this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately [May 14, 2009]." [2009 c 495 § 17.]

Captions and part headings not law -- 2007 c 343: See RCW 70.118B.900.

Findings -- 1993 c 492: "The legislature finds that our health and financial security are jeopardized by our ever increasing demand for health care and by current health insurance and health system practices. Current health system practices encourage public demand for unneeded, ineffective, and sometimes dangerous health treatments. These practices often result in unaffordable cost increases that far exceed ordinary inflation for essential care. Current total health care expenditure rates should be sufficient to provide access to essential health care interventions to all within a reformed, efficient system.

The legislature finds that too many of our state's residents are without health insurance, that each year many individuals and families are forced into poverty because of serious illness, and that many must leave gainful employment to be eligible for publicly funded medical services. Additionally, thousands of citizens are at risk of losing adequate health insurance, have had insurance canceled recently, or cannot afford to renew existing coverage.

The legislature finds that businesses find it difficult to pay for health insurance and remain competitive in a global economy, and that individuals, the poor, and small businesses bear an inequitable health insurance burden.

The legislature finds that persons of color have significantly higher rates of mortality and poor health outcomes, and substantially lower numbers and percentages of persons covered by health insurance than the general population. It is intended that chapter 492, Laws of 1993 make provisions to address the special health care needs of these racial and ethnic populations in order to improve their health status.

The legislature finds that uncontrolled demand and expenditures for health care are eroding the ability of families, businesses, communities, and governments to invest in other enterprises that promote health, maintain independence, and ensure continued economic welfare. Housing, nutrition, education, and the environment are all diminished as we invest ever increasing shares of wealth in health care treatments.

The legislature finds that while immediate steps must be taken, a long-term plan of reform is also needed." [1993 c 492 § 101.]

Intent -- 1993 c 492: "(1) The legislature intends that state government policy stabilize health services costs, assure access to essential services for all residents, actively address the health care needs of persons of color, improve the public's health, and reduce unwarranted health services costs to preserve the viability of nonhealth care businesses.

(2) The legislature intends that:

(a) Total health services costs be stabilized and kept within rates of increase similar to the rates of personal income growth within a publicly regulated, private marketplace that preserves personal choice;

(b) State residents be enrolled in the certified health plan of their choice that meets state standards regarding affordability, accessibility, cost-effectiveness, and clinical efficaciousness;

(c) State residents be able to choose health services from the full range of health care providers, as defined in RCW 43.72.010(12), in a manner consistent with good health services management, quality assurance, and cost effectiveness;

(d) Individuals and businesses have the option to purchase any health services they may choose in addition to those included in the uniform benefits package or supplemental benefits;

(e) All state residents, businesses, employees, and government participate in payment for health services, with total costs to individuals on a sliding scale based on income to encourage efficient and appropriate utilization of services;

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(f) These goals be accomplished within a reformed system using private service providers and facilities in a way that allows consumers to choose among competing plans operating within budget limits and other regulations that promote the public good; and

(g) A policy of coordinating the delivery, purchase, and provision of health services among the federal, state, local, and tribal governments be encouraged and accomplished by chapter 492, Laws of 1993.

(3) Accordingly, the legislature intends that chapter 492, Laws of 1993 provide both early implementation measures and a process for overall reform of the health services system." [1993 c 492 § 102.]

Short title -- Severability -- Savings -- Captions not law -- Reservation of legislative power -- Effective dates -- 1993 c 492: See RCW 43.72.910 through 43.72.915.

Severability -- 1992 c 34: See note following RCW 69.07.170.

Effective date -- Severability -- 1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Savings -- 1985 c 213: "This act shall not be construed as affecting any existing right acquired or liability or obligation incurred under the sections amended or repealed in this act or under any rule, regulation, or order adopted under those sections, nor as affecting any proceeding instituted under those sections." [1985 c 213 § 31.]

Effective date -- 1985 c 213: "This 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 June 30, 1985." [1985 c 213 § 33.]

Severability -- 1967 ex.s. c 102: See note following RCW 43.70.130.

Rules and regulations -- Visual and auditory screening of pupils: RCW 28A.210.020.

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RCW 18.64.005

State board of pharmacy — Powers and duties.

The board shall:

- (1) Regulate the practice of pharmacy and enforce all laws placed under its jurisdiction;
- (2) Prepare or determine the nature of, and supervise the grading of, examinations for applicants for pharmacists' licenses;
- (3) Establish the qualifications for licensure of pharmacists or pharmacy interns;
- (4) Conduct hearings for the revocation or suspension of licenses, permits, registrations, certificates, or any other authority to practice granted by the board, which hearings may also be conducted by an administrative law judge appointed under chapter 34.12 RCW;
- (5) Issue subpoenas and administer oaths in connection with any hearing, or disciplinary proceeding held under this chapter or any other chapter assigned to the board;
- (6) Assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs, controlled substances, and the practice of pharmacy, or any other laws or rules under its jurisdiction;
- (7) Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the board;
- (8) Adopt rules establishing and governing continuing education requirements for pharmacists and other licensees applying for renewal of licenses under this chapter;
- (9) Be immune, collectively and individually, from suit in any action, civil or criminal, based upon any disciplinary proceedings or other official acts performed as members of such board. Such immunity shall apply to employees of the department when acting in the course of disciplinary proceedings;
- (10) Suggest strategies for preventing, reducing, and eliminating drug misuse, diversion, and abuse, including professional and public education, and treatment of persons misusing and abusing drugs;
- (11) Conduct or encourage educational programs to be conducted to prevent the misuse, diversion, and abuse of drugs for health care practitioners and licensed or certified health care facilities;
- (12) Monitor trends of drug misuse, diversion, and abuse and make periodic reports to disciplinary boards of licensed health care practitioners and education, treatment, and appropriate law enforcement agencies regarding these trends;
- (13) Enter into written agreements with all other state and federal agencies with any responsibility for controlling drug misuse, diversion, or abuse and with health maintenance organizations, health care service contractors, and health care providers to assist and promote coordination of agencies responsible for ensuring compliance with controlled substances laws and to monitor observance of these laws and cooperation between these agencies. The department of social and health services, the department of labor and industries, and any other state agency including licensure disciplinary boards, shall refer all apparent instances of over-prescribing by practitioners and all apparent instances of legend drug overuse to the department. The department shall also encourage such referral by health maintenance organizations, health service contractors, and health care providers.

[1990 c 83 § 1; 1989 1st ex.s. c 9 § 409; 1984 c 153 § 2; 1981 c 67 § 21; 1979 c 90 § 2; 1973 1st ex.s. c 18 § 2; 1963 c 38 § 18; 1935 c 98 § 3; RRS § 10132-2. Formerly RCW 43.69.030.]

Notes:

Section captions not law -- 1990 c 83: "Section captions as used in this act do not constitute any part of the law." [1990 c 83 § 3.]

Effective date -- Severability -- 1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

Effective dates -- Severability -- 1981 c 67: See notes following RCW 34.12.010.

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RX PRODUCT LISTINGS

OK

ABC

PROD. MFR	NDC	AWP	DP	QBC	PROD. MFR	NDC	AWP	DP	QBC	PROD. MFR	NDC	AWP	DP	QBC
(25X10ML LATEX-FREE)					(McNeil)					(PCCA)				
14.5% 40 ml 25s	00409-0680-75	19.50	17.00		SOL. IV (M.D.V.)					POW, NA (USP, ANHYDROUS)				
(VIAL, FLUPTOP, BULK PKG)					0.9%, 30 ml	43072-0569-30	1.49		EE	1 gm	61927-1144-00	0.08		
23.4%, 100 ml 25s	00409-1141-02	51.60	45.25		(Phys Total Care)					(Spectrum Pharmacy) See SODIUM CITRATE ANHYDROUS				
250 ml 12s	00409-1130-02	49.10	42.96		(Hospira)					(Spectrum Pharmacy) See SODIUM CITRATE DIHYDRATE				
(Hospira) See SYREX					SOL. IV (1X750ML LATEX-FREE)				AP	SODIUM CITRATE ANHYDROUS (Spectrum Pharmacy)				
(Latic)					0.9%, 750 ml	54668-0115-01	74.31			sodium citrate				
GRA, NA (U.S.P.N.F.)					(Quixley Care Prod)					POW, NA (E.C.C.)				
1000 gm	62991-1312-02	33.00			(Hospira)					100 gm	49452-6707-01	35.70		
(Mallinckrodt Lab)					SOL. IV (1X30ML LATEX-FREE)				AP	(U.S.P.)				
GRA, NA (U.S.P.)					0.9%, 30 ml	35356-0141-30	6.32			100 gm	49452-6711-01	32.73		
500 gm	00406-7532-04	17.67			SODIUM CHLORIDE CONCENTRATE (Amer Reagent)					500 gm	49452-6707-02	49.88		
2500 gm	00406-7532-06	52.67			sodium chloride					(U.S.F.)				
(McNeil) See SODIUM CHLORIDE BACTERIOSTATIC					SOL. IV (S.D.V., PF)					500 gm	49452-6711-02	48.65		
(Medall) See NORMAL SALINE FLUSH					23.4%, 30 ml 25s	00517-2030-25	35.94			2500 gm	49452-6707-03	187.25		
(Medisca)					(BULK PACKAGE)					(U.S.P.)				
POW, NA (USP)					23.4%, 100 ml 25s	00517-2900-25	93.75			2500 gm	49452-6711-03	171.33		
100 gm	38779-0679-05	21.50			(APP)					2500 gm	49452-6711-03	171.33		
(U.S.P.)					SOL. IV (S.D.V., PF)					SODIUM CITRATE DIHYDRATE (Baker, J.T.)				
500 gm	38779-0679-06	31.50			23.4%, 30 ml	63373-0147-30	7.39			sodium citrate				
(USP)					(MAXIVIAL, BULK PACK, PF)					GRA, NA (U.S.F., F.C.C. & C.S.)				
1000 gm	38779-0679-09	46.50			23.4%, 100 ml	63373-0088-61	9.30			500 gm	10105-3848-01	10.79		
2500 gm	38779-0679-01	87.00			200 ml	63373-0088-63	17.10			2500 gm	10108-3849-05	82.09		
(Parl) See HYPER-SAL					SODIUM CHLORIDE FLUSH (AMSINO)					POW, NA (U.S.P., F.C.C.)				
(PCCA)					sodium chloride					500 gm	10106-3660-01	10.97		
GRA, NA (USP)					SOL. IV (IN 3ML SD SYRINGE, PF)					2500 gm	10108-3850-05	91.20		
1 gm	51927-1047-00	0.07			0.9%, 2.5 ml 180s	68883-0300-01	570.60			(Gallipot)				
(Spectrum Pharmacy)					(IN 12ML SD SYRINGE, PF)					GRA, NA (U.S.P., N.F.)				
GRA, NA (U.S.P.)					0.9%, 3 ml 180s	68883-0300-16	556.20			454 gm	51552-0101-06	10.08		
500 gm	49452-6690-01	31.33			(IN 6ML SD SYRINGE, PF)					2770 gm	51652-0101-04	29.68		
2500 gm	49452-6690-02	79.80			0.9%, 3 ml 180s	68883-0300-03	576.00			(Mallinckrodt Lab)				
(2000 gm)	49452-6690-03	248.68			(IN 12ML SD SYRINGE, PF)					CRY, NA (U.S.P.)				
POW, NA, 500 gm	49452-6700-01	45.33			0.9%, 5 ml 180s	68883-0300-05	649.80			500 gm	00406-0734-04	29.53		
2500 gm	49452-6700-02	125.30			(IN 6ML SD SYRINGE, PF)					2500 gm	00406-0734-06	95.94		
(Vial Signs) See VASCEVE SODIUM CHLORIDE					0.9%, 5 ml 180s	68883-0300-04	586.00			(Medisca)				
(Allscripts)					(IN 12ML SD SYRINGE, PF)					POW, NA (U.S.P.)				
(Hospira)					SOL. IV (3ML W/CANNULA)					100 gm	38779-0643-05	22.50		
SOL. IV (AMP)					0.9%, 2 ml	04450-8011-02	3.70	3.08		500 gm	38779-0643-08	34.50		
0.9%, 10 ml 25s	54569-1527-00	71.31		EE	(3ML PRE-FILLED SYRINGE)					(USP)				
(ORX)					0.9%, 2 ml	04450-8901-02	2.90	2.47		2500 gm	38779-0643-01	67.00		
(Hospira)					(6ML W/CANNULA)					(Spectrum Pharmacy)				
SOL. IV (10MLX25)					0.9%, 3 ml	04450-8012-03	3.84	3.70		GRA, NA (U.S.P.)				
0.9%, 10 ml 25s	55045-3710-01	50.00			(16ML PRE-FILLED SYRINGE)					500 gm	49452-6710-01	39.03		
(Phys Total Care)					0.9%, 3 ml	04450-0903-03	3.05	2.54		2500 gm	49452-6710-02	115.33		
SOL. IV (AMP, PF)					(12ML W/CANNULA)					12000 gm	49452-6710-03	511.00		
0.9%, 3 ml 100s	54868-6028-00	50.04			0.9%, 5 ml	04450-6013-05	4.10	3.42		SODIUM COBALINITRITE (Baker, J.T.)				
(R. (PL LATEX-FREE)					(12ML PRE-FILLED SYRINGE)					POW, NA (A.C.S., REAGENT)				
0.9%, 500 ml 74s	54468-0710-02	91.08		AT	0.9%, 10 ml	04450-8014-10	4.50	3.75		125 gm	10106-3658-04	69.78		
IV (150X5ML)					(12ML PRE-FILLED SYRINGE)					500 gm	10108-3658-01	209.55		
0.9%, 5 ml 150s	54868-2527-00	90.58			0.9%, 10 ml	04450-0905-05	3.30	2.75		SODIUM CYANIDE (Baker, J.T.)				
(PF)					(12ML W/CANNULA)					GRA, NA (A.C.S., REAGENT)				
0.9%, 10 ml 25s	54868-4464-00	15.95		FE	0.9%, 10 ml	04450-8014-10	4.50	3.75		125 gm	10108-3662-04	23.90		
(20X25ML)					(12ML PRE-FILLED SYRINGE)					500 gm	10108-3662-01	42.02		
0.9%, 20 ml 25s	54868-5714-00	57.76			SODIUM CHLORIDE/TETRASTARCH					(Mallinckrodt Lab)				
(NORMAL SALINE, 48X50ML)					(Hospira) See VOLUVEN					GRA, NA (A.C.S.)				
0.9%, 50 ml 48s	54868-0710-05	33.12			SOL. IV (PREMIX, 24X100ML)					500 gm	00408-7616-04	29.13		
(NORMAL SALINE, 48X100ML)					0.9%-80 mg/100 ml					SODIUM DENHYDROACETATE (PCCA)				
0.9%, 100 ml 48s	54868-0710-03	123.59		EE	100 ml 24s	00409-3470-23	263.57	230.64		POW, NA, 1 gm	51927-3581-00	0.41		
(NORMAL SALINE, 24X250ML)					(PREMIX LATEX-FREE)					SODIUM DESOXYCHOLATE				
0.9%, 250 ml 24s	54868-0710-06	133.96			0.9%-50 mg/50 ml	00409-3469-13	229.54	200.88		(PCCA) See OXYCHOLIC ACID				
500 ml	54868-0710-01	91.06		EE	50 ml 24s					SODIUM DICHROMATE				
1000 ml	54868-0710-00	64.30		EE	SODIUM CHROMATE					(Baker, J.T.) See SODIUM CHROMATE TETRAHYDRATE				
(NORMAL SALINE, 12X1000ML)					(Baker, J.T.) See SODIUM CHROMATE TETRAHYDRATE					SODIUM DICHROMATE DIHYDRATE (Baker, J.T.)				
0.9%, 1000 ml 12s	54868-0710-04	83.75			sodium chromate					sodium dichromate				
(Southwood)					CRY, NA (REAGENT)					CRY, NA (A.C.S., REAGENT)				
(USP)					SOL. IV (100 ucl/ml)					125 gm	10106-3672-04	77.35		
SOL. IV (10MLX100)					2.5 ml	00019-8370-25	676.80	564.00		500 gm	10106-3672-01	138.20		
0.9%, 10 ml 100s	56016-4995-01	69.34			SODIUM CHROMATE TETRAHYDRATE (Baker, J.T.)					SODIUM DITHIONITE (Baker, J.T.)				
SODIUM CHLORIDE BACTERIOSTATIC (Amer Reagent)					sodium chromate					POW, NA (PURIFIED)				
sodium chloride					CRY, NA (REAGENT)					500 gm	10106-3712-01	31.82		
SOL. IV (M.D.V.)					125 gm	10106-3640-04	55.26			2500 gm	10106-3712-05	103.62		
0.9%, 30 ml 25s	00517-0648-25	35.94		EE	500 gm	01106-3640-01	100.37			SODIUM EDECRIN (Abn)				
(Hospira)					SODIUM CITRATE					(Charynate sodium)				
SOL. IV (25X10ML, LS-PLASTIC)					(Baker, J.T.) See SODIUM CITRATE DIHYDRATE					PDS, IV, 50 mg, na	26010-0210-27	162.50		
0.9%, 10 ml 25s	00409-1966-17	21.50	19.00	AP	(Chira) See TRICITRASI					SODIUM FERRIC GLUCONATE COMPLEX				
(25X10ML LATEX-FREE)					(Gallipot) See SODIUM CITRATE DIHYDRATE					(Watson) See FERPECIT				
0.9%, 10 ml 25s	00409-1966-04	16.20	14.25	AP	(Humco)					SODIUM FLUORIDE (Amend)				
(25X20ML LATEX-FREE)					GRA, NA (U.S.P.)					POW, NA (U.S.P.)				
0.9%, 20 ml 25s	00409-1966-05	21.60	19.00	AP	454 gm	00335-2691-01	12.59			125 gm	17377-8898-04	8.40		
(FLUPTOP, LS-PLASTIC)					(Mallinckrodt Lab) See SODIUM CITRATE DIHYDRATE					500 gm	17317-0608-01	19.80		
0.9%, 30 ml 25s	00409-1966-14	38.10	33.25	AP	(Medisca) See SODIUM CITRATE DIHYDRATE					2770 gm	17317-8508-05	84.00		
(VIAL, FLUPTOP, PLASTIC)														
0.9%, 30 ml 25s	00409-1966-07	16.50	14.50	AP										

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§ 246-879-010. Definitions.**Washington Administrative Code****Title 246. Health, Department of****PROFESSIONAL STANDARDS AND LICENSING****Chapter 246-879. Pharmaceutical wholesalers**

All regulations passed and filed through February 17, 2010

§ 246-879-010. Definitions

- (1) "Full line wholesaler" means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required see **WAC 246-879-080**) and nonprescription drugs (over-the-counter - OTC see **WAC 246-879-070**) to a licensed pharmacy or other legally licensed or authorized person.
- (2) "Over-the-counter only wholesaler" means any wholesaler authorized by the board to possess and sell nonprescription (OTC) drugs to any outlets licensed for resale.
- (3) "Controlled substances wholesaler" means a licensed wholesaler authorized by the board to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.
- (4) "Export wholesaler" means any wholesaler authorized by the board to export legend drugs and nonprescription (OTC) drugs to foreign countries.
- (5) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (6) "Blood component" means that part of the blood separated by physical or mechanical means.
- (7) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
- (8) "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.
- (9) "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.

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(10) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription:

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(c) The sale, purchase, or trade of blood and blood components intended for transfusion.

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner.

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

(11) "Wholesale distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

History. Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-010, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-010, filed 3/2/82.

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WAC 246-290-220

Drinking water materials and additives.

(1) All materials shall conform to the ANSI/NSF Standard 61 if in substantial contact with potable water supplies. For the purposes of this section, "substantial contact" means the elevated degree that a material in contact with water may release leachable contaminants into the water such that levels of these contaminants may be unacceptable with respect to either public health or aesthetic concerns. It should take into consideration the total material/water interface area of exposure, volume of water exposed, length of time water is in contact with the material, and level of public health risk. Examples of water system components that would be considered to be in "substantial contact" with drinking water are filter media, storage tank interiors or liners, distribution piping, membranes, exchange or adsorption media, or other similar components that would have high potential for contacting the water. Materials associated with components such as valves, pipe fittings, debris screens, gaskets, or similar appurtenances would not be considered to be in substantial contact.

(2) Materials or additives in use prior to the effective date of these regulations that have not been listed under ANSI/NSF Standard 60 or 61 may be used for their current applications until the materials are scheduled for replacement, or that stocks of existing additives are depleted and scheduled for reorder.

(3) Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60. The maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice.

(4) Any products used to coat, line, seal, patch water contact surfaces or that have substantial water contact within the collection, treatment, or distribution systems must comply with the appropriate ANSI/NSF Standard 60 or 61. Application of these products must comply with recommendations contained in the product certification.

(5) The department may accept continued use of, and proposals involving, certain noncertified chemicals or materials on a case-by-case basis, if all of the following criteria are met:

(a) The chemical or material has an acknowledged and demonstrable history of use in the state for drinking water applications;

(b) There exists no substantial evidence that the use of the chemical or material has caused consumers to register complaints about aesthetic issues, or health related concerns, that could be associated with leachable residues from the material; and

(c) The chemical or material has undergone testing through a protocol acceptable to the department and has been found to not contribute leachable compounds into drinking water at levels that would be of public health concern.

(6) Any pipe, pipe fittings, fittings, fixtures, solder, or flux used in the installation or repair of a public water system shall be lead-free:

(a) This prohibition shall not apply to leaded joints necessary for the repair of cast iron pipes; and

(b) Within the context of this section, lead-free shall mean:

(i) No more than eight percent lead in pipes and pipe fittings;

(ii) No more than two-tenths of one percent lead in solder and flux; and

(iii) Fittings and fixtures that are in compliance with standards established in accordance with 42 USC 300g-6(e).

[Statutory Authority: RCW 43.20.050 (2) and (3) and 70.119A.080 . 03-08-037, § 246-290-220, filed 3/27/03, effective 4/27/03. Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-220, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-290-220, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-131, filed 2/17/88.]

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§ 246-290-460. Fluoridation of drinking water.

Washington Administrative Code

Title 246. Health, Department of

WATER SYSTEMS

Chapter 246-290. Group A public water supplies

Part 5. WATER SYSTEM OPERATIONS

All regulations passed and filed through February 17, 2010

§ 246-290-460. Fluoridation of drinking water

(1) Purveyors shall obtain written department approval of fluoridation treatment facilities before placing them in service.

(2) Where fluoridation is practiced, purveyors shall maintain fluoride concentrations in the range 0.8 through 1.3 mg/L throughout the distribution system.

(3) Where fluoridation is practiced, purveyors shall take the following actions to ensure that concentrations remain at optimal levels and that fluoridation facilities and monitoring equipment are operating properly:

(a) Daily monitoring.

(i) Take daily monitoring samples for each point of fluoride addition and analyze the fluoride concentration. Samples must be taken downstream from each fluoride injection point at the first sample tap where adequate mixing has occurred.

(ii) Record the results of daily analyses in a monthly report format acceptable to the department. A report must be made for each point of fluoride addition.

(iii) Submit monthly monitoring reports to the department within the first ten days of the month following the month in which the samples were collected.

(b) Monthly split sampling.

(i) Take a monthly split sample at the same location where routine daily monitoring samples are taken. A monthly split sample must be taken for each point of fluoride addition.

(ii) Analyze a portion of the sample and record the results on the lab sample submittal form and on the monthly report form.

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(iii) Forward the remainder of the sample, along with the completed sample form to the state public health laboratory, or other state-certified laboratory, for fluoride analysis.

(iv) If a split sample is found by the certified lab to be:

(A) Not within the range of 0.8 to 1.3 mg/l, the purveyor's fluoridation process shall be considered out of compliance.

(B) Differing by more than 0.30 mg/l from the purveyor's analytical result, the purveyor's fluoride testing shall be considered out of control.

(4) Purveyors shall conduct analyses prescribed in subsection (3) of this section in accordance with procedures listed in the most recent edition of *Standard Methods for the Examination of Water and Wastewater*.

(5) The purveyor may be required by the department to increase the frequency, and/or change the location of sampling prescribed in subsection (3) of this section to ensure the adequacy and consistency of fluoridation.

History. Statutory Authority: RCW 43.02.050 43.20.050. 99-07-021, § 246-290-460, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-290-460, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-235, filed 2/17/88. Statutory Authority: RCW 43.20.050. 83-19-002 (Order 266), § 248-54-235, filed 9/8/83.

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