Supreme Court No. 93188-7

Court of Appeals, Division I, No. 73225-1-I

SUPREME COURT OF THE STATE OF WASHINGTON

ANNA CHESTER,

Petitioner,

vs.

DEEP ROOTS ALDERWOOD, LLC, a Washington company; and BONNIE GILLSON,

Respondents.

PETITION FOR REVIEW

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A. IDENTITY OF PETITIONER

This petition for review is filed on behalf of Plaintiff/Petitioner Anna Chester (Chester).

B. COURT OF APPEALS DECISION

Chester seeks review of the published Court of Appeals decision affirming summary judgment in favor of Defendants/Respondents Deep Roots Alderwood, LLC (Deep Roots), and Bonnie Gillson (Gillson). *See Chester v. Deep Roots Alderwood, LLC,* — Wn. App. —, — P.3d —, 2016 WL 1305200 (Wn. App., Div. I, Apr. 4, 2016). A copy of the decision is reproduced in the Appendix at pages A-1 to A-7.

C. ISSUES PRESENTED FOR REVIEW

This action arises from severe personal injuries suffered by Chester after a licensed tattoo artist (Gillson) gave her a tattoo using non-sterile ink contaminated with disease-causing bacteria at a licensed tattoo parlor (Deep Roots). The Court of Appeals decision raises the following issues:

1. Are tattoo artists and tattoo parlors subject to liability for negligence as a matter of law (negligence per se) under RCW 5.40.050(3) for use of non-sterile tattoo ink contaminated with disease-causing bacteria? In particular:

    a. Does the use of non-sterile tattoo ink contaminated with disease-causing bacteria

violate WAC 246-145-050(18), which prohibits the use of inks that are banned or restricted by the U.S. Food & Drug Administration (FDA), given that the federal Food, Drug & Cosmetic Act regulates tattoo ink as a "cosmetic," *see* 21 U.S.C. § 321(i), prohibits the delivery or receipt of "adulterated" cosmetics in interstate commerce, *see id.* § 331(c), and deems a cosmetic to be adulterated if it contains any substance deleterious to human health such as bacteria, *see id.* § 361(a)-(c)? And/or:

b. Does the use of non-sterile tattoo ink contaminated with disease-causing bacteria violate WAC 246-145-050(1), which requires the use of "sterile instruments and aseptic techniques at all times" during a tattoo procedure, where the phrase "aseptic technique" is defined to mean "a procedure that prevents contamination of any object or person," WAC 246-145-010(2), and the undisputed medical understanding of sterile instruments and aseptic techniques is incompatible with injecting non-sterile tattoo ink contaminated with disease-causing bacteria into a person's body?

2. Does a licensed tattoo parlor have a non-delegable duty to comply with the foregoing requirements under WAC 308-22-020, which provides "[e]very licensee shall comply with the requirements established by the department of health under WAC 246-145-015, 246-145-050, and 246-145-060"?

3. Did the lower courts err in refusing to consider undisputed medical testimony that injecting non-sterile tattoo ink into a person's body is incompatible with "sterile instruments and aseptic techniques" required by WAC 246-145-050(1) and defined by WAC 246-145-010(2)?

4. Apart from issues of negligence per se under RCW 5.40.050(3), should the Court hold that tattoo artists and tattoo parlors have a duty to use sterile tattoo ink grounded in simple negligence principles, even though the use of sterile ink does not appear to be standard in the tattoo industry?

D. STATEMENT OF THE CASE

On September 13, 2011, Chester received a tattoo from Gillson at Deep Roots' tattoo parlor. Gillson used non-sterile ink containing disease-causing bacteria to apply the tattoo. It appears that the bacterial contamination occurred during manufacture of the ink, and she did not have actual knowledge that the ink was contaminated. However, Gillson had a choice of either sterile or non-sterile ink, and used non-sterile ink. CP 210, 353, 359, 368, 385, 393-97. The bacteria in the ink caused the destruction of Chester's kidneys at age 21. She now requires kidney dialysis for life or a kidney transplant. CP 253-55.

Chester filed suit against Gillson and Deep Roots alleging both negligence per se under RCW 5.40.050(3) and simple negligence. The negligence per se statute provides in pertinent part:

> A breach of a duty imposed by statute, ordinance, or administrative rule shall not be considered negligence per se, but may be considered by the trier of fact as evidence of negligence; ***however, any breach of duty as provided by statute, ordinance, or administrative rule relating to ... sterilization of needles and instruments used by persons***

> ***engaged in the practice of body art, body piercing, tattooing, or electrology, or other precaution against the spread of disease, as required under RCW 70.54.350 ... shall be considered negligence per se.***

RCW 5.40.050(3) (ellipses & emphasis added).[1]

The "other precaution against the spread of disease" referenced in the negligence per se statute incorporates regulations adopted by the Department of Health governing the tattoo industry. *See* RCW 70.54.350(1).[2] The regulations are based in part on consideration of "standard precautions for infection control, as recommended by the United States centers for disease control[.]" RCW 70.54.340. They codify what are described as "universal precautions" that must be used by persons licensed to practice tattooing. WAC 246-145-050.[3]

One such precaution is that "[i]nks or pigments must not be banned or restricted by the FDA[.]" WAC 246-145-050(18) (brackets & ellipses added). The federal Food, Drug & Cosmetic Act bans and restricts tattoo ink contaminated with bacteria. The Act

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[1] The full text of RCW 5.40.050 is reproduced in the Appendix.

[2] The full text of RCW 70.54.350 is reproduced in the Appendix.

[3] The full text of WAC 246-145-050 is reproduced in the Appendix.

regulates tattoo ink as a cosmetic,[4] and bans and restricts the delivery or receipt of adulterated cosmetics.[5] Under the Act, adulterated cosmetics include those contaminated with bacteria.[6]

Another universal precaution against the spread of disease applicable to tattoo artists and tattoo parlors in the State of Washington is the requirement to "[u]se sterile instruments and

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[4] *See* 21 U.S.C. § 321(i) (defining "cosmetic" to mean "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles"); *see also* U.S. Food & Drug Administration, Tattoos & Permanent Makeup: Fact Sheet (Aug. 22, 2012) (stating "FDA considers the inks used in intradermal tattoos ... to be cosmetics"; ellipses added). The full text of 21 U.S.C. § 321 and the FDA Fact Sheet are reproduced in the Appendix.

[5] *See* 21 U.S.C. § 331(a) & (c) (prohibiting "[t]he introduction or delivery for introduction into interstate commerce of any ... cosmetic that is adulterated" and "the receipt in interstate commerce of any ... cosmetic that is adulterated ... and the delivery or proffered delivery thereof for pay or otherwise"; brackets & ellipses added). Delivery and receipt of an adulterated cosmetic are distinguished from the act of adulteration itself. *See* 21 U.S.C. § 331(b). The full text of 21 U.S.C. § 331 is reproduced in the Appendix.

[6] 21 U.S.C. § 361(a)-(c) (providing "[a] cosmetic shall be deemed to be adulterated—(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual .... (b) If it consists in whole or in part of any filthy, putrid, or decomposed substance. (c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"; brackets & ellipses added); *see also* U.S. Food & Drug Administration, Warning Letter to Gemdo Cosmetics Inc. (Apr. 16, 2015) (stating presence of bacteria in cosmetics causes these products to be considered adulterated within the meaning of 21 U.S.C. § 361); U.S. Food & Drug Administration, Warning Letter to Vienna Beauty Products (May 17, 2012) (similar); U.S. Food & Drug Administration, Warning Letter to Carrington Laboratories, Inc. (Dec. 5, 2005) (similar); U.S. Food & Drug Administration, Warning Letter to The Master's Miracle, Inc. (June 9, 2005) (similar). The full text of 21 U.S.C. § 361 and the cited FDA Warning Letters regarding bacterial contamination of cosmetics are reproduced in the Appendix.

aseptic techniques at all times during a procedure." WAC 246-145-050(1) (brackets added). The phrase "aseptic technique" is defined to mean "a procedure that prevents contamination of any object or person." WAC 246-145-010(2).[7] Chester submitted undisputed testimony from her treating physician, whose qualifications were not challenged, that the concepts of "sterile" and "aseptic technique" are well known in the medical community, and that these concepts are incompatible with injecting non-sterile tattoo ink into a person's body. *See* CP 366-97.

The superior court dismissed Chester's negligence per se and simple negligence claims against Gillson and Deep Roots on summary judgment, and the Court of Appeals affirmed. The appellate court determined that Chester did not state a negligence per se claim based on FDA restrictions on adulterated cosmetics because:

> the FDCA does not create a private right of action. 21 U.S.C. § 337. Furthermore, the Act does not impose penalties on retailers who deliver adulterated cosmetics in good faith. 21 U.S.C. § 333(c).

Chester, 2016 WL 1305200, at *4. The court did not explain why the lack of a private right of action or the existence of a partial

[7] The full text of WAC 246-145-010 is reproduced in the Appendix.

defense to certain regulatory actions by the FDA should eliminate negligence per se liability.[8] The court did not acknowledge that the good faith defense to civil penalties does not extend to criminal liability,[9] nor does it eliminate the FDA's restrictions on adulterated cosmetics such as tattoo ink contaminated with disease-causing bacteria.[10]

The court further determined that Chester did not state a negligence per se claim based on the regulation requiring the use of sterile instruments and aseptic technique because this requirement does not, in the court's estimation, entail a duty to use sterile ink.

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[8] WAC 246-145-050(18) adopts FDA standards for banning and restricting adulterated tattoo ink. It does not adopt FDA standards for regulatory actions or defenses thereto.

[9] *See, e.g., United States v. Park*, 421 U.S. 658, 672-73 (1975) (indicating 21 U.S.C. § 331 "does not ... make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud'"; ellipses added); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1526 (E.D.N.Y.) (stating "criminal penalties attach to any person who causes a violation under 21 U.S.C. § 331" and "criminal liability attaches without any proof of intent, knowledge, or awareness of wrongdoing," citing *Park, supra*), *aff'd without op.*, 751 F.2d 373 (2d Cir. 1984).

[10] In a footnote earlier in its opinion, the court incorrectly stated that "[t]he FDA does not require that tattoo inks be sterile." *Chester*, at *2 n.2 (citing Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), *Tattoo-Associated Nontuberculous Mycobacterial Skin Infections-Multiple States*, 2011-12 (Aug. 24, 2012), vol. 61, no. 33, 653-656). The MMWR, which is reproduced in the Appendix, is from a different agency (the CDC rather than the FDA), is not legally authoritative, and does not establish the proposition for which it is cited. The MMWR actually says: "No *specific* FDA regulatory requirement *explicitly* provides that tattoo inks must be sterile." MMWR, at 653 & 655 (emphasis added). The requirement is arguably *implicit* in the prohibition of adulterated cosmetics. In any event, the problem with the ink used on Chester was not simply that it was non-sterile, but also that it was adulterated with disease-causing bacteria. The court did not dispute that cosmetics adulterated with disease-causing bacteria are *specifically* and *explicitly* banned and restricted by the FDA.

See Chester, at *3. In reaching this conclusion, the court rejected the undisputed medical testimony regarding the meaning of "sterile" and "aseptic technique" as legal conclusions. *See id.*, at *5-6.

Lastly, the court rejected Chester's simple negligence claim on grounds that the apparent standard of the tattoo industry does not require the use of sterile ink, and "Chester has not shown that sterile ink was widely available at the time in question, that claims of sterility were reliable, or that tattoo artists had the means to test ink for contamination and sterilize it on site." *Chester*, at *4. The court did not otherwise dispute that sterile ink was available for purchase by tattoo artists and tattoo parlors, nor did it elaborate on how widely it would have to be available or how reliably sterile it would have to be to give rise to a tort duty. *See id.*

From the Court of Appeals decision, Chester timely seeks review in this Court.

E. ARGUMENT WHY REVIEW SHOULD BE ACCEPTED

1. The decision below conflicts with precedent from this Court regarding the relationship between a statutory cause of action and negligence per se, creating uncertainty regarding the effect of a violation of a statute or regulation in any negligence case.

Negligence per se means negligence as a matter of law based upon violation of a statute or regulation. *See Kness v. Truck Trailer Equip. Co.*, 81 Wn. 2d 251, 255, 501 P.2d 285 (1972); *see also* 6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 60.01.01 (6th ed.).[11] The Court of Appeals decision below ties negligence per se liability to the existence of a "private right of action" for violation of a statute or regulation. *Chester*, at *4. This conflicts with the Court's decision in *Mina v. Boise Cascade Corp.*, 104 Wn. 2d 696, 703-04, 710 P.2d 184 (1985), addressing the relationship between negligence per se liability and a private right of action.

Mina involved a claim of negligence per se arising from violation of former RCW 46.61.560, which prohibited stopping a vehicle on the roadway outside of incorporated cities and towns. *See id.*, 104 Wn. 2d at 703 n.1 (quoting statute). In the course of its opinion, the Court stated:

[11] The negligence per se pattern jury instruction, WPI 60.01.01, is reproduced in the Appendix.

> Although RCW 46.61.560 does not provide for a private cause of action, this court has long held that a violation of a traffic statute can constitute negligence per se. *Portland-Seattle Auto Freight, Inc. v. Jones,* 15 Wash.2d 603, 131 P.2d 736 (1942); *Engelker v. Seattle Elec. Co.,* 50 Wash. 196, 96 P. 1039 (1908). ***In utilizing the doctrine of negligence per se, a court will substitute a statutory standard of conduct for the less restrictive common law standard of reasonableness even though the legislative enactment does not explicitly apply to a private suit***. *Herberg v. Swartz,* 89 Wash.2d 916, 922, 578 P.2d 17 (1978). *See generally* Thayer, *Public Wrong and Private Action,* 27 Harv.L.Rev. 317 (1914).

Id. at 703-04 (citations in original; emphasis added). This quotation directly contradicts the decision below.

The quoted language from *Mina* represents a holding because the Court's recognition that the existence of a private right of action is not a prerequisite to negligence per se liability was essential to its subsequent analysis of whether negligence per se liability applied to the facts of that particular case. *See id.* at 704-07. While the analysis of the applicability of negligence per se liability in *Mina,* based on the Restatement (Second) of Torts § 286 (1965), appears to have been superseded by the enactment of the negligence per se statute, RCW 5.40.050, nothing in the statute supersedes the Court's discussion of the relationship between a private right of action and negligence per se liability. On the

contrary, the statute expressly incorporates the phrase "negligence per se," indicating that the legislature intended to preserve the common law concept of negligence per se liability even while it limited its application to cases such as this one. *See Rettkowski v. Department of Ecology,* 128 Wn. 2d 508, 518, 910 P.2d 462 (1996) (stating "[w]hen a term is well known to the common law, the Legislature is presumed to have intended the term to mean what it was understood to mean at common law"; brackets added).

The conflict between the decision below and *Mina* warrants review under RAP 13.4(b)(1). In addition, the potential for confusion resulting from the decision below is an issue of substantial public interest that should be determined by this Court under RAP 13.4(b)(4). Other than the decision below, Chester has been able to identify no other reported decision in the State of Washington hinging negligence per se liability upon the existence of a private right of action. There is no reason for negligence per se liability in cases where a private right of action is otherwise available for the same violation of a statute or regulation, and the effect of the decision below is to effectively eliminate negligence per se liability. Moreover, the decision below even calls into question whether any violation of a statute or regulation can serve as

evidence of negligence under the negligence per se statute, in the absence of a private right of action. The Court should accept review to resolve this uncertainty.[12]

2. The decision below conflicts with precedent from this Court regarding the interpretation of technical terms and terms of art in statutes and regulations.

The Court of Appeals below declined to consider undisputed testimony from Chester's treating physician regarding the meaning of sterile instruments and aseptic technique within the medical community, and on de novo review affirmed the superior court's decision striking portions of the testimony. *Chester*, at *5-6. This conflicts with this Court's precedent regarding the interpretation of technical terms and terms of art in statutes and regulations. For example, in *State v. Nw. Magnesite Co.,* 28 Wn. 2d 1, 48 & 57, 182 P.2d 643 (1947), a case involving interpretation of former Rem. Rev. Stat. § 8025, requiring payment of royalties for mining on

[12] The Court of Appeals decision below also tied the existence of negligence per se liability to a good faith defense to civil penalties under 21 U.S.C. § 331(c). As noted above, this is not a defense to a violation of the Food, Drug & Cosmetic Act, only certain civil penalties. In any event, this defense is irrelevant to the grounds for negligence per se liability in this case, namely that the non-sterile ink contaminated with disease-causing bacteria used by Gillson and Deep Roots on Chester is an adulterated cosmetic banned and restricted by the FDA. *See* WAC 246-145-050(18). The only defense to negligence per se liability appears to be justification or excuse, i.e., the violation of a statute or regulation "is not negligence if it is due to some cause beyond the violator's control that ordinary care could not have guarded against." WPI 60.01.01.

public land less "costs of transportation and treatment," the Court explained why it is necessary to consider expert testimony regarding the meaning of technical terms and terms of art:

> It now becomes necessary to determine the meaning of the words 'transportation' and 'treatment' mentioned in the statute. The meaning of the words, they not having been defined by the legislature, do not admit of statutory construction, but must be shown by evidence. That knowledge must be obtained from the evidence of men learned in the profession or business of mining and quarrying. Judges are not chemists, scientists, geologists, or botanists. They are not experts in the field of lumbering, agriculture, mining, electricity, or any of numerous activities of life in which men and women devote their entire time to the study of one enterprise. Judges devote their entire life study to applying the principles of law to factual situations, and to the interpretation of statutes. The courts of the United States are unanimous in holding that the information relative to the meaning of undefined words in a statute must be obtained from experts in the business or work under consideration. Technical words, or terms of art relating to trade, when used in the statute dealing with the subject matter of such trade, are to be taken in their technical sense. Sutherland, Statutory Construction, 3d Ed., vol. 2, p. 437, § 4919; 50 Am.Jur. 438, § 413.

(Citations in original.) This rule is well-attested in many of this Court's cases, including cases involving the interpretation of medical words or phrases used in a statute. *See Gorre v. City of Tacoma*, 184 Wn. 2d 30, 36-39, 357 P.3d 625 (2015) (interpreting "respiratory disease" in RCW 51.32.185(1)(a) according to medical meaning, rather than ordinary meaning). The same rules of

interpretation apply to regulations as well as statutes. *See Demetrio v. Sakuma Bros. Farms, Inc.*, 183 Wn. 2d 649, 655, 355 P.3d 258 (2015).

The Court of Appeals' refusal to consider undisputed medical testimony regarding the meaning of "sterile instruments and aseptic technique" in this case conflicts with the foregoing authority, warranting review under RAP 13.4(b)(1). Chester's treating health care provider attested to the fact recognized in the medical community (which also coincides with common sense) that an instrument ceases to be "sterile" when it is dipped into or filled with a non-sterile and contaminated substance, and a technique ceases to be "aseptic" when it involves injecting a non-sterile and contaminated substance into a person's body.

Consideration of such testimony is consistent with the regulations governing the tattoo industry in Washington. The regulations were prompted by health concerns stemming from the risk of infecting those receiving tattoos with blood-borne pathogens. *See* RCW 70.54.320. The regulations presume that tattoos are performed using nontoxic ink.[13] The regulations are

[13] *See* RCW 70.54.330(4) (defining "[t]attooing" to mean "the indelible mark, figure, or decorative design introduced by insertion of *nontoxic* dyes or pigments

expressly based on consideration of "standard precautions for infection control, as recommended by the United States centers for disease control[.]" RCW 70.54.340. The regulations "establish standard universal precautions for preventing the spread of diseases by using sterilization procedures and infection control in the practices of ... tattooing." WAC 246-145-001; *see also* WAC 246-145-010(2) (defining "aseptic technique" in terms of "a procedure that *prevents* contamination of any object or person"; emphasis added). The regulations use technical medical words and phrases such as "sterile" and "aseptic technique." WAC 246-145-050(1). The Court should accept review to confirm that expert medical testimony regarding these terms is properly considered under the circumstances.

3. The question of whether tattoo artists and tattoo parlors should have a tort duty to use sterile ink presents a substantial question of public interest that should be decided by this Court.

The Court of Appeals below declined to recognize a duty grounded in simple negligence principles to use sterile ink when performing a tattoo. This presents an issue of substantial public interest that should be determined by this Court under RAP

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into or under the subcutaneous portion of the skin upon the body of a live human being for cosmetic or figurative purposes"; emphasis added).

13.4(b)(4), especially given the concerns about blood-borne pathogens and infectious diseases underlying the regulation of tattoo artists and parlors in the State of Washington, and the prevalence of tattoos. *See* Appendix, at A-60 (noting that 21% of Americans have tattoos and documenting health risks); *id.* at A-41 (documenting health risks).

While the standard of the tattoo industry apparently does not call for the use of sterile ink, the industry standard is not dispositive. *See Helling v. Carey*, 83 Wn. 2d 514, 519 P.2d 981 (1974) (imposing duty grounded in negligence to administer simple glaucoma test despite standard of the industry). As Judge Learned Hand famously stated in *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2nd Cir. 1947), a duty in tort arises from a risk-benefit analysis involving the probability of harm, the gravity of the resulting harm, and the burden of adequate precautions. The Court should accept review to determine whether tattoo artists and tattoo parlors have a duty to use sterile ink under this analysis.[14]

[14] As noted above, while the Court of Appeals questioned whether sterile ink is "widely available," and whether marketing claims about sterility were "reliable," the court did not dispute that sterile ink is available, and it did not elaborate on how widely it would have to be available or how reliably sterile it would have to be to give rise to a tort duty. *See Chester,* at *4.

F. CONCLUSION

Chester asks the Court to grant her petition for review, reverse the summary judgment in favor of Gillson and Deep Roots, and remand this case for trial.

Respectfully submitted this 4th day of May, 2016.

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CERTIFICATE OF SERVICE

The undersigned does hereby declare the same under oath and penalty of perjury of the laws of the State of Washington:

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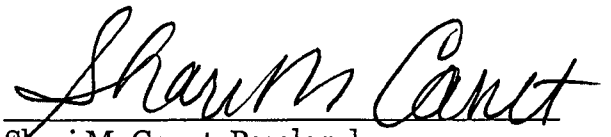

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APPENDIX

2016 WL 1305200
Only the Westlaw citation is currently available.
Court of Appeals of Washington,
Division 1.

Anna CHESTER, Appellant,
v.
DEEP ROOTS ALDERWOOD, LLC, a Washington Corporation; and Bonnie Gillson, Respondents.

No. 73225–1–I.
|
April 4, 2016.

Synopsis

Background: Patron brought action against tattoo parlor and tattoo artist for negligence, alleging that she suffered an adverse reaction after being tattooed with ink that appeared to have been contaminated during manufacture. The Superior Court, Snohomish County, Linda C. Krese, J., entered summary judgment in favor of parlor and artist. Patron appealed.

Holdings: The Court of Appeals, Spearman, C.J., held that:

[1] parlor and artist were not negligent per se, absent any law that created a duty to use sterile ink;

[2] parlor and artist did not breach a duty of reasonable care by failing to ensure that ink was sterile; and

[3] medical expert's comments on the artist's standard of care were inadmissible.

Affirmed.

West Headnotes (10)

[1] **Negligence**
Elements in General
272 Negligence
272I In General
272k202 Elements in General

To survive summary judgment on a negligence claim, a plaintiff has the burden to produce evidence that the defendant owed her a duty of care and breached that duty, and she also has to show that the breach resulted in injury and was the proximate cause of that injury.

Cases that cite this headnote

[2] **Negligence**
Trades, Special Skills and Professions
Products Liability
Negligence or Fault
Products Liability
Miscellaneous Products
272 Negligence
272IX Trades, Special Skills and Professions
272k321 In General
313A Products Liability
313AII Elements and Concepts
313Ak114 Negligence or Fault
313A Products Liability
313AIII Particular Products
313Ak282 Miscellaneous Products

Tattoo parlor and tattoo artist, who allegedly used ink that appeared to have been contaminated during manufacture and which caused patron to have an adverse reaction, were not negligent per se, absent any statute or regulation that created a duty to use sterile ink. Federal Food, Drug, and Cosmetic Act, §§ 310, 303(c), 21 U.S.C.A. §§ 337, 333(c); West's RCWA 5.40.050(3), 18.300.010(18), 70.54.330(4); WAC 246-145-050(1).

Cases that cite this headnote

[3] **Appeal and Error**
Cases Triable in Appellate Court
30 Appeal and Error
30XVI Review
30XVI(F) Trial De Novo
30k892 Trial De Novo
30k893 Cases Triable in Appellate Court
30k893(1) In General

The Court of Appeals reviews questions of statutory interpretation de novo.

Cases that cite this headnote

[4] **Administrative Law and Procedure**
Construction

15A Administrative Law and Procedure
15AIV Powers and Proceedings of Administrative Agencies, Officers and Agents
15AIV(C) Rules, Regulations, and Other Policymaking
15Ak412 Construction
15Ak412.1 In General

The same principles apply to the interpretation of regulations as to the interpretation of statutes.

Cases that cite this headnote

[5] **Negligence**
Trades, Special Skills and Professions

Products Liability
Negligence or Fault

Products Liability
Miscellaneous Products

272 Negligence
272IX Trades, Special Skills and Professions
272k321 In General
313A Products Liability
313AII Elements and Concepts
313Ak114 Negligence or Fault
313A Products Liability
313AIII Particular Products
313Ak282 Miscellaneous Products

Tattoo parlor and tattoo artist, who allegedly used ink that appeared to have been contaminated during manufacture and which caused patron to have an adverse reaction, did not breach a duty of reasonable care by failing to ensure that ink was sterile, absent any evidence that sterile ink was widely available at the time in question, that claims of sterility of ink were reliable, or that tattoo artists had the means to test ink for contamination and sterilize it.

Cases that cite this headnote

[6] **Appeal and Error**
Cases Triable in Appellate Court

30 Appeal and Error
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30k892 Trial De Novo
30k893 Cases Triable in Appellate Court
30k893(1) In General

The de novo standard of appellate review applies to evidentiary rulings on admissibility.

Cases that cite this headnote

[7] **Evidence**
Opinions and Conclusions in General

157 Evidence
157XII Opinion Evidence
157XII(A) Conclusions and Opinions of Witnesses in General
157k471 Conclusions and Matters of Opinion or Facts
157k471(2) Opinions and Conclusions in General

A witness may not draw conclusions of law. ER 704.

Cases that cite this headnote

[8] **Evidence**
Subjects of Opinion Evidence in General

157 Evidence
157XII Opinion Evidence
157XII(A) Conclusions and Opinions of Witnesses in General
157k474.5 Subjects of Opinion Evidence in General

Statutory interpretation is the province of the court and is not a proper subject of testimony. ER 704.

Cases that cite this headnote

[9] **Evidence**
Matters Directly in Issue

157 Evidence
157XII Opinion Evidence
157XII(B) Subjects of Expert Testimony
157k506 Matters Directly in Issue

Medical expert's comments on the standard of care of a tattoo artist and his opinion that a regulation requiring the use of sterile instruments includes a requirement to use sterile ink constituted an inadmissible legal opinion, in negligence action brought by patron of tattoo parlor, who allegedly had an adverse reaction to ink that appeared to have been contaminated during manufacture; expert did not claim to

be a tattoo artist or tattoo expert, and expert did not merely explain the term "sterile" as used in the regulation, but he also stated that it "seems unambiguous" that regulation prohibited the use of any non-sterile ink by requiring "sterile instruments" and then concluded that, in the circumstances of the present case, sterile instruments were not used. ER 704; WAC 246–145–050(1).

Cases that cite this headnote

[10] Evidence

Due Care and Proper Conduct in General

157 Evidence
157XII Opinion Evidence
157XII(C) Competency of Experts
157k538 Due Care and Proper Conduct in General

Expert knowledge of the profession at issue is necessary to testify to the standard of care within that profession.

Cases that cite this headnote

Appeal from Snohomish Superior Court; Honorable Linda C. Krese.

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PUBLISHED OPINION

SPEARMAN, C.J.

***1** ¶ 1 Anna Chester suffered an adverse reaction after being tattooed with ink that appears to have been contaminated with bacteria when the tattoo artist received it from the distributor. Chester brought negligence claims against the tattoo artist and the tattoo parlor, arguing that they had a duty to use sterile ink. The trial court dismissed her claims on summary judgment and Chester appeals. We affirm, because neither the regulations governing the tattoo industry nor the common law impose a duty to use sterile ink.

FACTS

¶ 2 Bonnie Gillson, a tattoo artist, applied a tattoo to Anna Chester at Deep Roots Alderwood, LLC, a shop specializing in tattoos and body piercing. For the black portion of the tattoo, Gillson used One brand tattoo ink. One was a popular ink that Gillson had used for about a year and a half without problem. She ordered the ink from Kingpin, a distributor from whom she ordered many tattoo supplies.

¶ 3 A few weeks after applying Chester's tattoo, Gillson learned that several of her clients were experiencing adverse reactions to the black ink portions of their tattoos. An investigation by King County Public Health traced the reactions to a particular bottle of One brand black tattoo ink. The investigation indicated that the ink had likely been contaminated during manufacture. Gillson contacted every client she tattooed during the period of time she used the contaminated bottle of ink. Most clients suffered only a minor skin irritation that did not require medical treatment.

¶ 4 Chester, however, suffered a serious reaction to the contaminated ink. She consulted a doctor who diagnosed a bacterial infection at the tattoo site and prescribed a course of antibiotics. The infection did not respond to the prescribed treatment. Chester's kidney function declined rapidly. In the opinion of Chester's doctor, the bacterial infection aggravated an underlying chronic kidney disease. Chester was eventually referred to an infectious disease specialist, Dr. Warren L. Dinges. Dinges successfully treated the infection. But before the infection was brought under control Chester's kidneys had failed, requiring her to begin dialysis.

¶ 5 Chester brought product liability and negligence claims against Gillson and Deep Roots. [1] To support her negligence claims, Chester relied on two declarations from her medical expert, Dinges. Gillson and Deep Roots moved to strike

Dinges's second declaration. The trial court granted the motion in part.

¶ 6 Gillson and Deep Roots moved for summary judgment. Chester conceded dismissal of her product liability claims, but opposed the motion as to her negligence claims. The trial court found as a matter of law that Chester's evidence failed to establish the essential elements of negligence and granted summary judgment for Gillson and Deep Roots. Chester appeals.

DISCUSSION

[1] ¶ 7 Chester argues that the trial court erred in finding that she did not show the elements of negligence. We review a decision on summary judgment de novo, engaging in the same inquiry as the trial court. *Camicia v. Howard S. Wright Constr. Co.,* 179 Wash.2d 684, 693, 317 P.3d 987 (2014). To survive summary judgment on a negligence claim, Chester had the burden to produce evidence that the respondents owed her a duty of care and breached that duty. *Hurley v. Port Blakely Tree Farms L.P.,* 182 Wash.App. 753, 773, 332 P.3d 469 (2014) *review denied,* 182 Wn.2d 2008 (2015), (citing *Crowe v. Gaston,* 134 Wash.2d 509, 514, 951 P.2d 1118 (1998)). She also had to show that the breach resulted in injury and was the proximate cause of that injury. *Id.*

***2 [2]** ¶ 8 Chester first argues that the respondents were negligent per se because they violated a statutory duty of care. Chester relies on RCW 5.40.050(3), under which the breach of tattooing regulations related to the use of sterile needles is negligence per se. She asserts that WAC 246.145.050(1), which requires that tattoo artists use "sterile instruments and aseptic techniques at all times during a procedure," imposes a duty to use sterile ink.

[3] [4] ¶ 9 We review questions of statutory interpretation de novo. *Pham v. Corbett,* 187 Wash.App. 816, 831, 351 P.3d 214 (2015) (citing *State v. Wentz,* 149 Wash.2d 342, 346, 68 P.3d 282 (2003). In interpreting statutes, our aim is to discern and implement the Legislature's intent. *Id.* (citing *State v. J.P.,* 149 Wash.2d 444, 450, 69 P.3d 318 (2003)). We begin with the plain language of the statute. *Id.* Where the plain language is unambiguous and the legislative intent is apparent, we " 'will not construe the statute otherwise.' " *Id.* (quoting *J.P.,* 149 Wash.2d at 450, 69 P.3d 318). Legislative intent may be discerned from the statutory scheme as a whole. *Id.* (quoting *Dep't of Ecology v. Campbell & Gwinn, LLC,* 146 Wash.2d 1, 11, 43 P.3d 4 (2002)). The same principles apply to the interpretation of regulations as to the interpretation of statutes. *Silverstreak, Inc., v. Washington State Dep't. of Labor and Industries,* 159 Wash.2d 868, 898, 154 P.3d 891 (2007).

¶ 10 The Legislature authorized the secretary of health to regulate the tattoo industry and instructed the secretary to adopt rules "in accordance with nationally recognized professional standards." RCW 70.54.340. The legislature further directed the secretary to "consider the standard precautions for infection control, as recommended by the United States centers for disease control." RCW 70.54.340. In compliance with these directives, the secretary of health adopted chapter 246–145 WAC to regulate electrology, body art, body piercing, and tattooing.

¶ 11 WAC 246–145–050 details 24 "universal precautions" applicable to tattoo artists and body piercers. Three subsections include sterilization requirements. Artists must use "sterile instruments and aseptic techniques at all times during a procedure." WAC 246–145–050(1). They must use only presterilized single-use disposable tattoo needles. WAC 246–145–050(2). Artists must obtain jewelry used in body piercing presterilized or sterilize the jewelry on site prior to the procedure. WAC 246–145–050(20). The regulation includes two provisions concerning tattoo ink. Tattoo artists must use single-use ink containers for each client to prevent contaminating the unused portion of ink. WAC 246–145–050(15). Artists may not use inks that are banned or restricted by the FDA. WAC 246–145–050(18). [2]

¶ 12 The next regulation, WAC 246–145–060, details the requirements for **"[s]terile procedures in body art, body piercing and tattooing."** The regulation repeats the requirement to use only single-use, presterilized disposable needles. WAC 246–145–060(1)(a). It requires artists to only reuse instruments intended for multiple use that have been cleaned and sterilized between clients. WAC 246–145–060(1)(c). The regulation gives specific requirements for sterilizing and storing reusable instruments. WAC 246–145–060(1)(c)–(g). The regulation includes no requirements for ink.

***3** ¶ 13 There is no regulation that, by its plain language, creates a duty to use sterile ink. The regulatory scheme as a whole indicates that the secretary carefully considered sterilization as it applies to the tattoo industry. The regulations require that some items be obtained presterilized and that

others be sterilized on site, according to detailed procedures. The secretary also considered tattoo ink and issued rules concerning what ink may be used and how ink must be dispensed.

¶ 14 Considering the detail of the regulatory scheme, the specific requirements concerning sterilization, and the attention given to tattoo ink, it is not reasonable to conclude that the secretary intended to require the use of sterile ink but couched that duty within the requirement to use sterile instruments and aseptic technique. We conclude that the plain language of the regulation is not ambiguous and the legislative intent is clear. There is not a regulatory requirement to use sterile ink.

¶ 15 Chester next argues that the definition section of RCW 70.54.330 is an independent basis for finding the respondents negligent per se. RCW 70.54.330(4) defines "tattooing" as an indelible mark "introduced by insertion of nontoxic dyes or pigments into or under the subcutaneous portion of the skin." Chester contends that this section creates a duty to use only nontoxic ink and that the respondents breached this duty by using contaminated ink. The respondents argue that the section does not apply to the negligence per se statute, RCW 5.40.050(3). We agree with the respondents.

¶ 16 RCW 5.40.050 establishes negligence per se for the breach of a duty created by statute or rule relating to "(3) sterilization of needles and instruments used by persons engaged in the practice of body art, body piercing, tattooing, or electrology, or other precaution against the spread of disease, as required under RCW 70.54.350." The referenced statute, RCW 70.54.350 states, "[a]ny person who practices electrology or tattooing shall comply with the rules adopted by the department of health under RCW 70.54.340." The negligence per se statute thus applies to the breach of any tattooing regulation having to do with precautions against the spread of disease. The definition of tattooing in RCW 70.54.330(4) is not such a regulation.

¶ 17 This reading is in harmony with other statutory and regulatory provisions defining tattooing. RCW 18.300.010, which became effective at the same time as the tattoo regulations, explicitly states that its definitions apply to RCW 5.40.050, the negligence per se statute. The statute defines "tattooing" as "to pierce or puncture the human skin with a needle or other instrument for the purpose of implanting an indelible mark." RCW 18.300.010(8). The regulations also use this definition. WAC 246–145–101(25). Neither the statutory nor the regulatory definition encompassed by the negligence per se statute includes the word "nontoxic."

*4 ¶ 18 At oral argument and in a statement of additional authorities, Chester also asserted that the respondents were negligent per se because they violated the Federal Food, Drug, and Cosmetic Act (FDCA). Chester argued that the respondents violated 21 U.S.C. § 331, which prohibits introducing or receiving in interstate commerce any adulterated cosmetic. This argument is without merit because the FDCA does not create a private right of action. 21 U.S.C. § 337. Furthermore, the Act does not impose penalties on retailers who deliver adulterated cosmetics in good faith. 21 U.S.C. § 333(c).

¶ 19 We conclude that Chester has not shown the existence of a statutory duty to use sterile ink and we reject her claim of negligence per se.

[5] ¶ 20 Chester argues in the alternative that she established the elements of common law negligence. Chester asserts that even if the respondents owed only a duty of reasonable care, they breached that duty by not using sterile ink or confirming that the ink was not contaminated.

¶ 21 Chester does not assert that sterile ink is the industry standard. But she argues that even if sterile ink is not routinely used, the risks associated with using contaminated ink far outweigh the burden of using sterile ink. She argues that the respondents thus breached a duty of reasonable care by failing to ensure the ink they used was sterile.

¶ 22 Chester relies on *Helling v. Carey,* 83 Wash.2d 514, 519 P.2d 981 (1974), in which the Supreme Court quoted Judge Learned Hand and followed his cost-benefit analysis. *Id.* at 519, 519 P.2d 981. In *Helling,* a 32–year–old patient became partially blind due to undetected glaucoma. *Id.* at 516, 519 P.2d 981. The defendant ophthalmologists presented evidence that glaucoma is uncommon in young patients and the industry standard was to administer routine glaucoma tests after the age of 40. *Id.* But the court held that, given the severity of glaucoma and the availability of a simple and harmless test to detect the disease, the doctors breached a duty by failing to administer the test. *Id.* at 519, 519 P.2d 981.

¶ 23 Chester's argument falls short because she glosses over the burden of using sterile ink. In *Helling,* it was undisputed that the ophthalmologists could easily administer a simple glaucoma test. *Helling,* 83 Wash.2d at 519, 519 P.2d 981.

Chester asserts that using sterile ink is similarly easy as "Gillson can simply order sterile rather than non-sterile ink...." Br. of Appellant at 23. She further argues that the respondents had not only a duty to purchase ink advertised as sterile, but also a duty to ensure that ink was in fact sterile. However, Chester has not shown that sterile ink was widely available at the time in question, that claims of sterility were reliable, or that tattoo artists had the means to test ink for contamination and sterilize it on site.

¶ 24 Chester presented evidence that Intenze brand tattoo ink was advertised as sterile about the time that Gillson purchased the One brand ink. She also produced the article *Microbial status and product labelling of 58 original tattoo inks* (2011) as evidence of the association between tattoo ink and bacterial infection. The article reports on a study of 58 inks for sale in the European market. Concerning those inks claiming to be sterile, the authors found that none of the claims could be verified and some were demonstrably false. The authors found that Intenze black ink, advertised as sterile, contained a high level of bacterial contamination.

***5** ¶ 25 The record includes a further example of an unreliable claim of sterility. At some point prior to March 2012, the One brand website claimed that its ink was sterile. An inspection determined that, although the manufacturer was having the ink treated with gamma radiation, the dosage of radiation was not sufficient to support the claim of sterility.

¶ 26 Chester has not shown that sterile ink was readily available or that claims of sterility were reliable. She offered no evidence that tattoo artists have the means to test ink for contamination or sterilize ink received from distributors. We conclude that *Helling* is distinguishable. Chester has not established that the respondents' duty of reasonable care required them to use sterile ink.

¶ 27 Chester also argues that the trial court erred in striking one paragraph of Dinges's second declaration and in considering another paragraph only as medical opinion. She argues that the court should have considered the declaration in its entirety and that the declaration is evidence that the respondents had a duty to use sterile ink.

[6] **[7]** **[8]** ¶ 28 The de novo standard applies to evidentiary rulings on admissibility. *Keck v. Collins,* 184 Wash.2d 358, 368, 357 P.3d 1080 (2015) (citing *Folsom v. Burger King,* 135 Wash.2d 658, 663, 958 P.2d 301 (1998)). Affidavits in support of a summary judgment motion must contain facts that would be admissible in evidence. CR 56(e). Statements in an affidavit are not inadmissible because they "embrace[ ] an ultimate issue to be decided by the trier of fact." ER 704. However, a witness may not draw "conclusion [s] of law." *Everett v. Diamonds,* 30 Wash.App. 787, 791, 638 P.2d 605 (1981). Statutory interpretation is the province of the court, and is not a proper subject of testimony. *Id.* at 792, 638 P.2d 605 (citing *Ball v. Smith,* 87 Wash.2d 717, 722–723, 556 P.2d 936 (1976)).

[9] ¶ 29 In his second declaration, Dinges comments on the use of "*sterile instruments and aseptic techniques at all times during a procedure* " as required by WAC 246–145–050(1). Dinges states:

> Regardless of the credentials of the person performing the injection, the requirement to "use sterile instruments ... at all times during a procedure" seems unambiguous to me. The only meaning that I can attach to that rule is that, if a tattoo artist inserts into a customer, by way of an instrument, understood to be a needle used to penetrate the surface of the skin, ink that is contaminated with bacteria, then clearly "sterile instruments" were not used at all times during the procedure because the instrument, meaning the instrument used to penetrate the customer's skin, was contaminated with bacteria.

Clerk's Papers (CP) at 369.

¶ 30 Chester asserts that the trial court erred in striking this passage as legal opinion. She argues that the statement that the tattoo needle was not "sterile" is a statement of fact, not a legal opinion. Chester further argues that this paragraph contains only explanations of the regulatory terms.

***6** ¶ 31 In the stricken paragraph, Dinges does not merely explain the term "sterile" or state that a tattoo needle is no longer sterile after it has come into contact with contaminated ink. Dinges states that it "seems unambiguous" that by requiring " 'sterile instruments' " the regulation prohibits the use of any non-sterile ink. (Quoting CP at 369). Dinges then draws the conclusion that, in the circumstances of the present case, "clearly 'sterile instruments' were not used." The paragraph both construes the regulation and reaches the legal conclusion that the respondents violated the regulation. Conclusions of law and statutory interpretation are not proper subjects for testimony. *Everett,* 30 Wash.App. at 791, 638 P.2d 605.

[10] ¶ 32 Chester next argues that the statement is admissible as Dinges's understanding of the standard of care and a breach of that standard. Chester quotes *White v. Kent Med. Ctr., Inc., P.S.*, 61 Wash.App. 163, 171, 810 P.2d 4 (1991), for the proposition that the standard of care and a breach of that standard " 'ordinarily must be shown by expert medical testimony.' " *White,* however, is inapposite because it involved a claim of medical negligence. *Id.* Expert knowledge of the profession at issue is necessary to testify to the standard of care within that profession. *Young v. Key Pharmaceutical. Inc.,* 112 Wash.2d a 216, 227–230, 112 Wash.2d 216, 770 P.2d 182 (1989) (pharmacist not qualified to testify that physicians breached their standard of care). Dinges does not claim to be a tattoo artist or an expert in tattooing. His testimony is therefore not admissible to establish the standard of care for tattoo artists. The trial court did not err in striking the paragraph as legal opinion.

¶ 33 Chester also argues that the trial court erred in considering the following paragraph of Dinges's declaration only as medical opinion:

> In my opinion the absolute minimum that is required for a tattoo artist (or any person intending to inject a substance into a person) to be able to claim the use of sterile instruments and aseptic technique at all times during the procedure is that the artist only use ink that is in fact sterile. In this case, the artist did not use ink that was in fact sterile because the black ink in Ms. Chester's tattoo was contaminated with bacteria.
>
> To ensure sterile instruments and aseptic technique throughout the procedure, the procedure has to start with sterile tattoo ink.

CP at 370.

¶ 34 Chester argues that the legislature directed the secretary of health to "consider the standard precautions for infection control, as recommended by the United States centers for disease control" (CDC). RCW 70.54.340. She asserts that this directive indicates that medical doctors and the secretary of health share the same understanding of sterility, and Dinges is qualified to testify to that shared understanding. She argues that the trial court erred in not considering the challenged paragraph to establish the elements of negligence.

*7 ¶ 35 Chester's argument fails because, while Dinges is qualified to testify to the meaning of the term "sterile," his statement goes beyond explaining the term. The challenged statement includes Dinges's opinion that the regulation requiring the use of sterile instruments and aseptic technique includes an unstated requirement to use sterile ink. To the extent Dinges interprets the statute, his statement is inadmissible because statutory interpretation is the province of the court. To the extent Dinges testifies to the standard of care, his testimony is inadmissible because he is not an expert in tattooing.

¶ 36 Chester's argument concerning the CDC does not change this result. The legislature instructed the secretary to adopt rules "in accordance with nationally recognized professional [tattoo] standards" and to "consider the standard precautions for infection control, as recommended by the United States centers for disease control." RCW 70.54.340. This instruction to the secretary does not impose CDC or other medical standards on tattoo artists. The secretary of health and medical professionals may share an understanding of sterility, as Chester asserts, but the secretary did not promulgate regulations imposing medical standards on tattoo artists. Dinges is a medical expert. We conclude that the trial court did not err in considering his statement as medical opinion, but not as evidence of duty and breach within the tattoo industry.

¶ 37 Affirmed.

WE CONCUR: VERELLEN and APPELWICK, JJ.

1 Chester also brought product liability claims against Kingpin and one of Kingpin's suppliers. These claims were not dismissed on summary judgment and are not before this court.

2 The FDA does not require that tattoo inks be sterile. *See* Centers for Disease Control, Morbidity and Mortality Weekly Report (MMWR), *Tattoo–Associated Nontuberculous Mycobacterial Skin Infections—Multiple States,* 2011–2012 (August 24, 2012) Vol. 61, No. 33, 653–656 at http://www.cdc.gov/mmwr/pdf/wk/mm6133.pdf

All Citations

--- P.3d ----, 2016 WL 1305200

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West's Revised Code of Washington Annotated
Title 5. Evidence (Refs & Annos)
Chapter 5.40. Proof--General Provisions (Refs & Annos)

West's RCWA 5.40.050

5.40.050. Breach of duty--Evidence of negligence--Negligence per se

Effective: July 1, 2010
Currentness

A breach of a duty imposed by statute, ordinance, or administrative rule shall not be considered negligence per se, but may be considered by the trier of fact as evidence of negligence; however, any breach of duty as provided by statute, ordinance, or administrative rule relating to: (1) Electrical fire safety, (2) the use of smoke alarms, (3) sterilization of needles and instruments used by persons engaged in the practice of body art, body piercing, tattooing, or electrology, or other precaution against the spread of disease, as required under RCW 70.54.350, or (4) driving while under the influence of intoxicating liquor or any drug, shall be considered negligence per se.

Credits
[2009 c 412 § 20, eff. July 1, 2010; 2001 c 194 § 5; 1986 c 305 § 901.]

Notes of Decisions (29)

West's RCWA 5.40.050, WA ST 5.40.050
Current with all laws from the 2015 Regular and Special Sessions and Laws 2016, chs. 1 and 2

End of Document

West's Revised Code of Washington Annotated
Title 70. Public Health and Safety (Refs & Annos)
Chapter 70.54. Miscellaneous Health and Safety Provisions (Refs & Annos)

West's RCWA 70.54.350

70.54.350. Electrology and tattooing--Practitioners to comply with rules--Penalty

Currentness

(1) Any person who practices electrology or tattooing shall comply with the rules adopted by the department of health under *RCW 70.54.340.

(2) A violation of this section is a misdemeanor.

Credits
[2001 c 194 § 4.]

West's RCWA 70.54.350, WA ST 70.54.350
Current with all laws from the 2015 Regular and Special Sessions and Laws 2016, chs. 1 and 2

End of Document

Washington Administrative Code
Title 246. Health, Department of
Chapter 246-145. Body Art, Body Piercing, Electrology and Tattooing Standards for Sterilization Procedures and Infection Control

WAC 246-145-010

246-145-010. Definitions.

Currentness

For the purpose of these rules, the following words and phrases have the following meanings unless the context clearly indicates otherwise.

(1) 'Antiseptic' means an agent that destroys disease causing microorganisms on human skin or mucosa.

(2) 'Aseptic technique' means a procedure that prevents contamination of any object or person.

(3) 'Bloodborne pathogens' means microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV), Hepatitis C virus (HBC) and human immunodeficiency virus (HIV).

(4) 'Body art' means the practice of invasive cosmetic adornment including the use of branding and scarification. Body art also includes the intentional production of scars upon the body. Body art does not include any health-related procedures performed by licensed health care practitioners under their scope of practice.

(5) 'Body piercing' means the process of penetrating the skin or mucous membrane to insert an object, including jewelry, for cosmetic purposes. Body piercing also includes any scar tissue resulting from or relating to the piercing. Body piercing does not include the use of stud and clasp piercing systems to pierce the earlobe in accordance with the manufacturer's directions and applicable FDA requirements. Body piercing does not include any health-related procedures performed by licensed health care practitioners under their scope of practice, nor does anything in this act authorize a person registered to engage in the business of body piercing to implant or embed foreign objects into the human body or otherwise engage in the practice of medicine.

(6) 'Branding' means inducing a pattern of scar tissue by use of a heated material (usually metal) to the skin creating a serious burn which eventually results in a scar.

(7) 'Department' means the department of licensing.

(8) 'Disinfectant' means a substance or solution, registered with the United States Environmental Protection Agency (EPA) that kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.

(9) 'Disinfect' or 'disinfection' means the destruction of disease-causing microorganisms on inanimate objects or surfaces, thereby rendering these objects safe for use or handling.

(10) 'Electrologist' means a person who practices the business of electrology for a fee.

(11) 'Electrology' means the process of permanently removing hair by using solid needle or probe electrode epilation, including:

(a) Thermolysis, being of shortwave, high frequency type;

(b) Electrolysis, being a galvanic type; or

(c) A combination of both which is accomplished by a superimposed or sequential blend.

(12) 'FDA' means United States Food and Drug Administration.

(13) 'Gloves' means single-use disposable medical grade gloves that are FDA approved.

(14) 'Hand sanitizer' means an alcohol-based sanitizer with a concentration of 60% to 95% ethanol or isopropanol.

(15) 'Jewelry' means any personal ornament inserted into a newly pierced area, which must be made of surgical implant-grade stainless steel, solid 14k or 18k white or yellow gold, niobium, titanium, or platinum, or a dense, low-porosity plastic, which is free of nicks, scratches, or irregular surfaces and has been properly sterilized prior to use.

(16) 'Licensee' means a shop, business or individual licensed to practice body art, body piercing or tattooing.

(17) 'Procedure(s)' means body art, body piercing, and tattooing procedures.

(18) 'Sanitize' means a procedure that reduces the level of microbial contamination so that the item or surface is considered safe.

(19) 'Scarification' means altering skin texture by cutting the skin and controlling the body's healing process in order to produce wounds, which result in permanently raised wheals or bumps known as keloids.

(20) 'Sharps' means any objects (sterile or contaminated) that may purposefully or accidentally cut or penetrate the skin or mucosa including, but not limited to, presterilized, single-use needles, scalpel blades, and razor blades.

(21) 'Sharps container' means a puncture-resistant, leak-proof container that can be closed for handling, storage, transportation, and disposal and that is labeled with the international biohazard symbol.

(22) 'Single-use' means products, instruments or items that are intended for one-time use and are disposed of after each use including, but not limited to, cotton swabs or balls, tissue or paper products, paper or plastic cups, gauze and sanitary coverings, razors, needles, scalpel blades, stencils, ink cups and protective gloves.

(23) 'Sterilization' means a process that destroys all forms of microbial life, including highly resistant bacterial spores.

(24) 'Sterilizer' means an apparatus that is registered and listed with the FDA for destroying all forms of microbial life, including highly resistant bacterial spores.

(25) 'Tattooing' means to pierce or puncture the human skin with a needle or other instrument for the purpose of implanting an indelible mark, or pigment into the skin.

(26) 'Universal precautions' is an approach to infection control as defined by the Center for Disease Control (CDC). According to the concept of universal precautions, all human blood and certain body fluids are treated as if known to be infectious for human immunodeficiency virus (HIV), Hepatitis B virus (HBV) and other bloodborne pathogens.

Credits

Statutory Authority: RCW 70.54.340. WSR 10-12-057, S 246-145-010, filed 5/27/10, effective 7/1/10; WSR 02-11-109, S 246-145-010, filed 5/20/02, effective 6/20/02.

Current with amendments adopted through the 16-07 Washington State Register dated, April 6, 2016.

WAC 246-145-010, WA ADC 246-145-010

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Washington Administrative Code
Title 246. Health, Department of
Chapter 246-145. Body Art, Body Piercing, Electrology and Tattooing Standards for Sterilization Procedures and Infection Control

WAC 246-145-050

246-145-050. Standard universal precautions for preventing the spread of disease in body art, body piercing, and tattooing.

Currentness

The following universal precautions must be used by persons licensed to practice body art, body piercing, and tattooing:

(1) Use sterile instruments and aseptic techniques at all times during a procedure.

(2) Use only presterilized single-use disposable needles for body piercing and tattooing on one client and then dispose of the needles immediately in a sharps container.

(3) Wear a clean outer garment and prevent hair from coming into contact with the client. All necklaces, bracelets, or other personal items must be removed or covered by the outer garment or gloves to prevent the item coming in contact with the client.

(4) Wash hands and wrists thoroughly in warm running water with soap for at least twenty seconds, scrub around and under fingernails, rinse completely and dry with a clean single-use towel or hand dryer. Handwashing must be done immediately before and after performing a procedure.

(5) Inspect hands for small cuts, sores and abrasions. If present, use a Seal-skin product or bandage.

(6) Licensees with weeping dermatitis or draining sores must avoid contact with clients and equipment until the weeping dermatitis or draining sores are healed.

(7) Wear gloves during procedures and while assembling instruments. Licensees must wash hands immediately before single-use disposable gloves are put on and after gloves are removed.

(8) Wear gloves to prepare the client's skin (washing and shaving) and then discard the gloves after completing the preparation. A new pair of gloves must be put on before continuing the procedure.

(9) Remove gloves immediately, wash hands or use a hand sanitizer, and put on new gloves, when gloved hands break aseptic technique (e.g., touching eyes, nose or mouth, answering the phone, opening a door, or retrieving an item from the floor) during a procedure, or when gloves are torn or have small pinholes.

(10) If a licensee sustains a needle stick, they shall resume the procedure with clean and sterile equipment after rewashing hands and putting on new gloves.

(11) Change gloves after contact with each client.

(12) Clean and disinfect chairs, tables, work spaces, counters, and general use equipment in the procedure area between each client. Follow manufacturers' instructions for proper use of disinfecting (or detergent) products.

(13) Use appropriate barrier films to cover all items gloved hands would normally come into contact with during a procedure. These items include, but are not limited to, machine heads, clip cords, spray bottles, seat adjustment controls, power control dials or buttons and work lamps.

(14) Use single-use stencils. Petroleum jellies, soaps and other products used in the application of stencils must be dispensed and applied using aseptic technique and in a manner to prevent contamination of the original container and its contents. The applicator must be single-use.

(15) Use only single-use pigment or ink containers for each client. Pigments and ink shall be dispensed from containers in a manner to prevent contamination to the unused portion. Individual containers of ink or pigment must be discarded after use.

(16) Use single-use razors during procedures and dispose of them in a sharps container.

(17) In the event of blood flow, use products that are single-use to control or check the blood flow or absorb the blood. Used products must be disposed of immediately in appropriate covered container. The use of styptic pens or alum solids to control blood flow is prohibited.

(18) Inks or pigments must not be banned or restricted by the FDA and must not be mixed with improper ingredients. Information indicating the source of all inks and pigments shall be available to the department upon request.

(19) Use single-use marking instruments or instruments sanitized by design, such as alcohol based ink pens, on intact skin that has been treated with an antiseptic solution. Any marking instrument that comes in contact with mucous membranes or broken skin shall be single-use.

(20) All jewelry, as defined in WAC 246-145-010, must be obtained in presterilized packaging from the manufacturer or be sterilized on-site prior to the procedure.

(21) Cleanse the client's skin before and after a procedure by washing the skin with a FDA registered antiseptic solution applied with a clean, single-use product. A sanitary covering must be placed over the procedure site when appropriate.

(22) Wearing new gloves open each package containing a sterile instrument in the presence of the client and handle each instrument in a manner to prevent contamination of the instrument.

(23) Prevent needlestick injuries by not recapping needles or breaking needles by hand and by not otherwise manipulating contaminated needles by hand.

(24) Disposal of sharps containers must comply with the local solid waste program through the licensee's local county health department.

Credits

Statutory Authority: RCW 70.54.340. WSR 10-12-057, S 246-145-050, filed 5/27/10, effective 7/1/10.

Current with amendments adopted through the 16-07 Washington State Register dated, April 6, 2016.

WAC 246-145-050, WA ADC 246-145-050

End of Document

6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 60.01.01 (6th ed.)

Washington Practice Series TM
Washington Pattern Jury Instructions--Civil
Database updated June 2013
Washington State Supreme Court Committee on Jury Instructions
Part VII. Statutory Violations
Chapter 60. Statutory Violations

WPI 60.01.01 Violation of Statute, Ordinance, or Administrative Rule—Negligence Per Se

The violation, if you find any, of a [statute] [ordinance] [administrative rule] relating to
[electrical fire safety]
[the use of smoke alarms]
[sterilization of needles and instruments used in the practice of [body art] [body piercing] [tattooing] [or] [electrology] [or other precaution against the spread of disease]]
[driving while under the influence of alcohol or any drug]
is negligence as a matter of law. Such negligence has the same effect as any other act of negligence.
[While such a violation is, generally speaking, negligence as a matter of law, it is not negligence if it is due to some cause beyond the violator's control that ordinary care could not have guarded against.]

NOTE ON USE

Use this instruction if the statute, ordinance, or administrative rule violated relates to one of the subject areas for which negligence per se applies under RCW 5.40.050: electrical fire safety, the use of smoke alarms, sterilization of needles or instruments used in the practice of body art, body piercing, tattooing, or electrology (or other precaution against the spread of disease), or driving while under the influence. For other violations, use WPI 60.03, Violation of Statute, Ordinance, Administrative Rule, or Internal Governmental Policy—Evidence of Negligence.

This instruction should be given immediately following the enactment or enactments to which it refers. To instruct the jury about the provisions of a particular enactment, see WPI 60.01, Statute, Ordinance, or Administrative Rule.

Regarding the instruction's language relating to improper sterilization of needles and instruments (or related activities), see the Comment's discussion of a 2009 statutory amendment and the possible need for additional instructions.

If a child has violated a statute, ordinance or administrative rule, see WPI 60.04, Standard of Conduct for Child—Violation of Statute, Ordinance, or Administrative Rule.

Use the bracketed material as applicable.

COMMENT

RCW 5.40.050, enacted as part of the Tort Reform Act of 1986, sets forth the general rule that violations of law may be evidence of negligence but do not constitute negligence per se. See WPI 60.03, Violation of Statute, Ordinance, Administrative Rule, or Internal Governmental Policy—Evidence of Negligence.

As an exception to that general rule, the statute provides in part: "[A]ny breach of duty as provided by statute, ordinance or administrative rule relating to electrical fire safety, the use of smoke alarms, sterilization of needles and instruments used by persons engaged in the practice of body art, body piercing, tattooing, or electrology, or other precaution against the spread of disease, as required under RCW 70.54.350, or driving while under the influence of intoxicating liquor or any drug, shall be considered negligence per se." RCW 5.40.050, as amended in Laws of 2009, Chapter 412, § 18 (effective July 1, 2010).

The 2009 amendment to RCW 5.40.050 changed the language relating to the sterilization of needles and instruments. Prior to the amendment, the statute read: "sterilization of needles and instruments used in tattooing or electrology as required under RCW 70.54.350." The pattern instruction may need to be revised for any case that arises under the former statutory language. Under either version of the statute, jurors may also need to be instructed with more specific language from RCW 70.54.350 or WAC 246-145-030, depending on the facts of the case.

To be consistent with other instructions the committee chose to use the phrase "violation of" rather than the phrase "breach of a duty imposed by" employed in RCW 5.40.050.

By restricting its use to enactments relating to specific subjects, RCW 5.40.050 significantly limits the doctrine of negligence per se. Prior to August 1, 1986, Washington followed the rule that the violation of any statute, ordinance, or administrative rule having the force of law constituted negligence per se.

Not every violation of an enactment or administrative rule relating to electrical fire safety, smoke alarms, improper sterilization of needles (and related activities), or driving while under the influence will constitute negligence per se. As a matter of law, the statute, ordinance, or administrative rule violated must still meet the test set forth in Restatement (Second) of Torts § 286 (1965) before the jury may be instructed concerning negligence per se. For further discussion, see the Comment to WPI 60.03, Violation of Statute, Ordinance, Administrative Rule, or Internal Governmental Policy—Evidence of Negligence.

Although the violation of certain statutes, ordinances, or administrative rules may be negligence per se, it does not follow that compliance always constitutes ordinary care. The statutory standard is only a minimum standard, and does not necessarily preclude a finding of negligence for failure to take additional precautions. See Robison v. Simard, 57 Wn.2d 850, 852, 360 P.2d 153 (1961); Prosser and Keeton on Torts § 36 (5th ed.).

RCW 5.40.050 does not mention justification or excuse as a basis to avoid the imposition of the doctrine. However, cases decided prior to the enactment of the 1986 law are clear that justification or excuse may be asserted by the violator. See Wood v. Chicago, M., St. P. & P. R. R. Co., 45 Wn.2d 601, 277 P.2d 345, 283 P.2d 688 (1954); Bissell v. Seattle Vancouver Motor Freight, Ltd., 25 Wn.2d 68, 168 P.2d 390 (1946).

[Current as of October 2010.]

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter II. Definitions (Refs & Annos)

21 U.S.C.A. § 321

§ 321. Definitions; generally

Effective: June 22, 2009
Currentness

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 (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia 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 Pharmacopeia, 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 purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means--

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136 et seq.], including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136 et seq.], this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of--

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if--

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than sections 342(a)(2)(B) and 346a of this title.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include--

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C.A. § 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C.A. § 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which--

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, 360ccc, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,--

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph (w) [1] of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of Title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and--

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information--

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent"--

(1) means--

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for--

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(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 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.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

***(ll)*(1)** The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 343(w) of this title.

(rr)(1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 353(g) of this title.

(3) The products described in paragraph (2) shall be subject to subchapter V of this chapter.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

CREDIT(S)

(June 25, 1938, c. 675, § 201, 52 Stat. 1040; July 22, 1954, c. 559, § 1, 68 Stat. 511; Sept. 6, 1958, Pub.L. 85-929, § 2, 72 Stat. 1784; July 12, 1960, Pub.L. 86-618, Title I, § 101, 74 Stat. 397; Oct. 10, 1962, Pub.L. 87-781, Title I, § 102(a), Title III, § 307(a), 76 Stat. 781, 796; July 15, 1965, Pub.L. 89-74, §§ 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub.L. 90-399, § 102, 82 Stat. 351; Oct. 24, 1968, Pub.L. 90-639, §§ 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub.L. 92-516, § 3(3), 86 Stat. 998; Apr. 22, 1976, Pub.L. 94-278, Title V, § 502(a)(2)(A), 90 Stat. 411; May 28, 1976, Pub.L. 94-295, § 3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, Pub.L. 95-203, § 4(b)(3), 91 Stat. 1453; Sept. 26, 1980, Pub.L. 96-359, § 3, 94 Stat. 1193; Nov. 16, 1988, Pub.L. 100-670, Title I, § 107(a)(1), 102 Stat. 3984; Nov. 8, 1990, Pub.L. 101-535, § 5(b), 104 Stat. 2362; Nov. 28, 1990, Pub.L. 101-629, § 16(b), 104 Stat. 4526; May 13, 1992, Pub.L.

102-282, § 6, 106 Stat. 161; June 16, 1992, Pub.L. 102-300, § 6(a), (b), 106 Stat. 240; Oct. 29, 1992, Pub.L. 102-571, Title I, § 107(1), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103-80, §§ 3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, Pub.L. 103-417, §§ 3(a), (b), 10(a), 108 Stat. 4327, 4332; Aug. 3, 1996, Pub.L. 104-170, Title IV, § 402, 110 Stat. 1513; Nov. 21, 1997, Pub.L. 105-115, Title I, §§ 121(a), 125(b)(2)(A), (e), 111 Stat. 2320, 2325, 2327; Oct. 30, 1998, Pub.L. 105-324, § 2(a), (c), 112 Stat. 3035, 3037; Jan. 4, 2002, Pub.L. 107-109, § 5(b)(1), 115 Stat. 1413; Oct. 26, 2002, Pub.L. 107-250, Title III, § 302(d), 116 Stat. 1619; Aug. 2, 2004, Pub.L. 108-282, Title I, § 102(b)(1), (5)(A), (B), Title II, § 203(c)(1), 118 Stat. 891, 902, 908; Sept. 27, 2007, Pub.L. 110-85, Title X, § 1005(c), 121 Stat. 968; June 22, 2009, Pub.L. 111-31, Div. A, Title I, § 101(a), 123 Stat. 1783.)

Notes of Decisions (423)

Footnotes

1 So in original. Probably should be "paragraph (v)".

21 U.S.C.A. § 321, 21 USCA § 321

Current through P.L. 114-124. Also includes P.L. 114-126 to 114-140, 114-142, 114-143, 114-145 and 114-146.

End of Document

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter III. Prohibited Acts and Penalties

21 U.S.C.A. § 331

§ 331. Prohibited acts

Effective: December 28, 2015
Currentness

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb-3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 379aa, 379aa-1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 2223 of this title (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 360ccc, 360ccc-1, 360ccc-2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section..[1] This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) Repealed. Pub.L. 105-115, Title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to

administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 or 387e of this title, the failure to provide any information required by section 360(j), 360(k), 387e(i), or 387e(j) of this title, or the failure to provide a notice required by section 360(j)(2) or 387e(i)(3) of this title.

(q)(1) The failure or refusal

(A) to comply with any requirement prescribed under section 360h, 360j(g), 387c(b), 387g, 387h, or 387*o* of this title;

(B) to furnish any notification or other material or information required by or under section 360i, 360j(g), 387d, 387i, or 387t of this title; or

(C) to comply with a requirement under section 360*l* or 387m of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, the distribution of drugs in violation of section 353(e) of this title, failure to comply with the requirements under section 360eee-1 of this title, the failure to comply with the requirements under section 360eee-3 of this title, as applicable, or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of Title 42; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food--

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted

(aa) The importation of a prescription drug in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure to comply with paragraph (7)(E) of section 374(g) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 350e of this title.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 379aa or 379aa-1 of this title) or the falsification of a serious adverse event report (as defined under section 379aa or 379aa-1 of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 282(j)(5)(B) of Title 42, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 282 of Title 42.

(3) The submission of clinical trial information under subsection (j) of section 282 of Title 42 that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 353c of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 355 of this title, a biological product licensed under section 262 of Title 42, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless--

(1) such drug or such biological product was marketed in food before any approval of the drug under section 355 of this title, before licensure of the biological product under such section 262 of Title 42, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with--

(A) a regulation issued under section 348 of this title prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 348(h) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 360b of this title.

(mm) The failure to submit a report or provide a notification required under section 350f(d) of this title.

(nn) The falsification of a report or notification required under section 350f(d) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 333(f) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 387k of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of--

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 387c of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 350g of this title.

(vv) The failure to comply with the requirements under section 350h of this title.

(ww) The failure to comply with section 350i of this title.

(xx) The refusal or failure to follow an order under section 350*l* of this title.

(yy) The knowing and willful failure to comply with the notification requirement under section 350f(h) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in section 384a of this title) does not have in place a foreign supplier verification program in compliance with such section 384a of this title.

(aaa) The failure to register in accordance with section 381(s) of this title.

(bbb) The failure to notify the Secretary in violation of section 360bbb-7 of this title.

(ccc)(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 353b of this title.

(2) With respect to a drug to be compounded pursuant to section 353a or 353b of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 353b of this title.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph--

(A) the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term "rinse-off cosmetic" includes toothpaste.

CREDIT(S)

(June 25, 1938, c. 675, § 301, 52 Stat. 1042; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, c. 613, § 1, 55 Stat. 851; July 6, 1945, c. 281, § 1, 59 Stat. 463; Mar. 10, 1947, c. 16, § 1, 61 Stat. 11; June 24, 1948, c. 613, § 1, 62 Stat. 582; Mar. 16, 1950, c. 61, § 3(b), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, c. 350, § 2, 67 Stat. 477; Sept. 6, 1958, Pub.L. 85-929, § 5, 72 Stat. 1788; July 12, 1960, Pub.L. 86-618, Title I, §§ 104, 105(a), 74 Stat. 403; Oct. 10, 1962, Pub.L. 87-781, Title I, §§ 103(c), 104(e)(1), 106(c), 114(a), Title III, § 304, 76 Stat. 784, 785, 788, 791, 795; July 15, 1965, Pub.L. 89-74, §§ 5, 9(c), 79 Stat. 232, 235; July 13, 1968, Pub.L. 90-399, § 103, 82 Stat. 352; Oct. 24, 1968, Pub.L. 90-639, § 2(b), 82 Stat. 1361; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(a), 84 Stat. 1281; Aug. 16, 1972, Pub.L. 92-387, § 4(e), 86 Stat. 562; May 28, 1976, Pub.L. 94-295, §§ 3(b), 4(b)(1), 7(b), 90 Stat. 576, 580, 582; Sept. 26, 1980, Pub.L. 96-359, § 5, 94 Stat. 1193; Oct. 27, 1986, Pub.L. 99-570, Title IV, § 4014(b)(2), 100 Stat. 3207-120; Apr. 22, 1988, Pub.L. 100-293, § 7(a), 102 Stat. 99; Nov. 3, 1990, Pub.L. 101-502, § 5(j), 104 Stat. 1289; Nov. 5, 1990, Pub.L. 101-508, Title IV, § 4755(c)(2), 104 Stat. 1388-210; June 16, 1992, Pub.L. 102-300, § 3(a)(1), 106 Stat. 239; Oct. 29, 1992, Pub.L. 102-571, Title I, § 107(2), (3), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103-80, § 3(c), 107 Stat. 775; Oct. 22, 1994, Pub.L. 103-396, § 2(b)(1), 108 Stat. 4154; Oct. 25, 1994, Pub.L. 103-417, § 10(b), 108 Stat. 4332; Apr. 26, 1996, Pub.L. 104-134, Title II, § 2103, 110 Stat. 1321-319; Aug. 3, 1996, Pub.L. 104-170, Title IV, § 403, 110 Stat. 1514; Oct. 9, 1996, Pub.L. 104-250, § 5(d), 110 Stat. 3156; Nov. 21, 1997, Pub.L. 105-115, Title I, § 125(a)(2)(A), (C), (b)(2)(B), Title II, §§ 204(b), 210(c), Title IV, §§ 401(b), 421, 111 Stat. 2325, 2336, 2345, 2364, 2380; Oct. 28, 2000, Pub.L. 106-387, § 1(a) [Title VII, § 745(d)(1)], 114 Stat. 1549, 1549A-39; June 12, 2002, Pub.L. 107-188, Title III, §§ 303(b), 304(d), 305(b), 306(c), 307(b), 321(b)(2), 322(b), 116 Stat. 665, 666, 668, 670, 672, 676, 677; Oct. 26, 2002, Pub.L. 107-250, Title II, § 201(d), 116 Stat. 1609; Nov. 24, 2003, Pub.L. 108-136, Div. A, Title XVI, § 1603(c), 117 Stat. 1690; Dec. 8, 2003, Pub.L. 108-173, Title XI, § 1121(b)(1), 117 Stat. 2469; Apr. 1, 2004, Pub.L. 108-214, § 2(b)(2)(A), 118 Stat. 575; Aug. 2, 2004, Pub.L. 108-282, Title I, § 102(b)(5)(C), (D), 118 Stat. 902; Aug. 10, 2005, Pub.L. 109-59, Title VII, § 7202(d), (e), 119 Stat. 1913; Dec. 22, 2006, Pub.L. 109-462, §§ 2(c), 3(b), 4(a), 120 Stat. 3472, 3475; Sept. 27, 2007, Pub.L. 110-85, Title VIII, § 801(b)(1), Title IX, §§ 901(d)(1), 912(a), Title X, § 1005(d), 121 Stat. 920, 939, 951, 968; June 22, 2009, Pub.L. 111-31, Div. A, Title I, § 103(b), 123 Stat. 1833; Jan. 4, 2011, Pub.L. 111-353, Title I, §§ 102(d)(1), 103(e), 105(c), 106(d), Title II, §§ 204(j), 206(d),

211(b), (c), Title III, § 301(b), 124 Stat. 3889, 3898, 3904, 3906, 3937, 3943, 3953, 3954; Pub.L. 112-144, Title VII, §§ 714(a), 715(a), July 9, 2012, 126 Stat. 1073, 1075; Pub.L. 113-54, Title I, § 103(a), Title II, § 206(a), Nov. 27, 2013, 127 Stat. 597, 639; Pub.L. 114-114, § 2(a), Dec. 28, 2015, 129 Stat. 3129.)

VALIDITY

<The United States Supreme Court has held section 301(f) of the Food, Drug, and Cosmetic Act, Act June 25, 1938, prohibiting a refusal to permit entry or inspection by federal officers, void for vagueness and to violate the Due Process Clause of the Fifth Amendment. U.S. v. Cardiff, U.S.Wash.1952, 344 U.S. 174, 73 S.Ct. 189, 97 L.Ed. 200.>

Notes of Decisions (235)

Footnotes

1 So in original.

21 U.S.C.A. § 331, 21 USCA § 331

Current through P.L. 114-124. Also includes P.L. 114-126 to 114-140, 114-142, 114-143, 114-145 and 114-146.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter VI. Cosmetics

21 U.S.C.A. § 361

§ 361. Adulterated cosmetics

Currentness

A cosmetic shall be deemed to be adulterated--

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution--This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

CREDIT(S)

(June 25, 1938, c. 675, § 601, 52 Stat. 1054; July 12, 1960, Pub.L. 86-618, Title I, § 102(c)(1), 74 Stat. 398; Oct. 29, 1992, Pub.L. 102-571, Title I, § 107(11), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103-80, § 3(x), 107 Stat. 778.)

Notes of Decisions (15)

21 U.S.C.A. § 361, 21 USCA § 361
Current through P.L. 114-124. Also includes P.L. 114-126 to 114-140, 114-142, 114-143, 114-145 and 114-146.

End of Document

Tattoos & Permanent Makeup: Fact Sheet

Consumers, manufacturers, tattoo artists, and health care providers may have questions on tattoos, permanent makeup, temporary tattoos, and henna (mehndi). Here is safety and regulatory information on these products.

Quick Guide

Learn the fast facts about types of tattoos, risks to consider, removals, and FDA's role in monitoring safety.

- **Tattoos & Permanent Makeup: Quick Guide (/downloads/Cosmetics/ProductsIngredients/Products/UCM460321.pdf)** (PDF: 536 KB)
- **Los Tatuajes y el Maquillaje Permanente: Una Guía (/downloads/Cosmetics/ProductsIngredients/Products/UCM460324.pdf)** (PDF: 522KB)

Safety and Regulatory Background

FDA considers the inks used in intradermal tattoos, including permanent makeup, to be cosmetics. When we identify a safety problem associated with a cosmetic, including a tattoo ink, we investigate and take action, as appropriate, to prevent consumer illness or injury. The pigments used in the inks are color additives, which are subject to premarket approval under the Federal Food, Drug, and Cosmetic Act. However, because of other competing public health priorities and a previous lack of evidence of safety problems specifically associated with these pigments, FDA traditionally has not exercised regulatory authority for color additives on the pigments used in tattoo inks. The actual practice of tattooing is regulated by local jurisdictions.

During 2003 and 2004, FDA became aware of more than 150 reports of adverse reactions in consumers to certain permanent makeup ink shades, and it is possible that the actual number of women affected was greater. The inks associated with this outbreak were voluntarily recalled by the company that marketed them in 2004. In the spring of 2012, we received reports of infections from contaminated inks, resulting in their recall and market withdrawal. In addition, concerns raised by the scientific community regarding the pigments used in tattoo inks have prompted FDA to investigate their safe use. FDA continues to evaluate the extent and severity of adverse events associated with tattooing and is conducting research on tattoo inks. As new information is assessed, we will consider whether additional actions are necessary to protect public health.

In addition to the reported adverse reactions, areas of concern include tattoo removal, infections that result from tattooing, and the increasing variety of pigments and diluents being used in tattooing. More than fifty different pigments and shades are in use, and the list continues to grow. Although a number of color additives are approved for use in cosmetics, none is approved for injection into the skin. Using an unapproved color additive in a tattoo ink makes the ink adulterated. Many pigments used in tattoo inks are not approved for skin contact at all. Some are industrial grade colors that are suitable for printers' ink or automobile paint.

Nevertheless, many individuals choose to undergo tattooing in its various forms. For some, it is an aesthetic choice or an initiation rite. Some choose permanent makeup as a time saver or because they have physical difficulty applying regular, temporary makeup. For others, tattooing is an adjunct to reconstructive surgery, particularly of the face or breast, to simulate natural pigmentation. People who have lost their eyebrows due to alopecia (a form of hair loss) may choose to have "eyebrows" tattooed on, while people with vitiligo (a lack of pigmentation in areas of the skin) may try tattooing to help camouflage the condition.

Whatever their reason, consumers should be aware of the risks involved in order to make an informed decision.

Risks Involved in Tattooing

The following are the primary complications that can result from tattooing:

- **Infection.** Unsterile tattooing equipment and needles can transmit infectious diseases, such as HIV, hepatitis, and skin infections caused by *Staphylococcus aureus* ("staph") and other bacteria*. Tattoos received at facilities not regulated by your state or at facilities that use unsterile equipment (or re-use ink) may prevent you from being accepted as a blood or plasma donor for twelve months. Infections also have resulted from contaminated tattoo inks, even when the tattoo artist has followed hygienic procedures. These infections can require prolonged treatment with antibiotics. To learn more, see **"Tattoo Inks Pose Health Risks." (/Cosmetics/ProductsIngredients/Products/ucm108530.htm)**
- **Removal problems.** Despite advances in laser technology, removing a tattoo is a painstaking process, usually involving several treatments and considerable expense. Complete removal without scarring may be impossible.
- **Allergic reactions.** Although FDA has received reports of numerous adverse reactions associated with certain shades of ink in permanent makeup, marketed by a particular manufacturer, reports of allergic reactions to tattoo pigments have been rare. However, when they happen they may be particularly troublesome because the pigments can be hard to remove. Occasionally, people may develop an allergic reaction to tattoos they have had for years.
- **Granulomas.** These are nodules that may form around material that the body perceives as foreign, such as particles of tattoo pigment.
- **Keloid formation.** If you are prone to developing keloids -- scars that grow beyond normal boundaries -- you are at risk of keloid formation from a tattoo. Keloids may form any time you injure or traumatize your skin. *Micropigmentation: State of the Art*, a book written by Charles Zwerling, M.D., Annette Walker, R.N., and Norman Goldstein, M.D., states that keloids occur more frequently as a consequence of tattoo removal.
- **MRI complications.** There have been reports of people with tattoos or permanent makeup who experienced swelling or burning in the affected areas when they underwent magnetic resonance imaging

(MRI). This seems to occur only rarely and apparently without lasting effects.There have also been reports of tattoo pigments interfering with the quality of the MRI image. This seems to occur mainly when a person with permanent eyeliner undergoes MRI of the eyes. However, the risks of avoiding an MRI when your doctor has recommended one are likely to be much greater than the risks of complications from an interaction between the MRI and tattoo or permanent makeup. Instead of avoiding an MRI, individuals who have tattoos or permanent makeup should inform the radiologist or technician.

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A Common Problem: Dissatisfaction

A common problem that may develop with tattoos is the desire to remove them. Removing tattoos and permanent makeup can be very difficult.

Although tattoos may be satisfactory at first, they sometimes fade. Also, if the tattooist injects the pigments too deeply into the skin, the pigments may migrate beyond the original sites, resulting in a blurred appearance.

Another cause of dissatisfaction is that the human body changes over time, and styles change with the season. The permanent makeup that may have looked flattering when first injected may later clash with changing skin tones and facial or body contours. People who plan to have facial cosmetic surgery are advised that the appearance of their permanent makeup may become distorted. The tattoo that seem stylish at the time may become dated and embarrassing later on. And changing tattoos or permanent makeup is not as easy as changing your mind.

Consult your healthcare provider about the best removal techniques for you.

Temporary Tattoos, Henna /Mehndi, and "Black Henna"

Temporary tattoos, such as those applied to the skin with a moistened wad of cotton, fade several days after application. FDA has issued an **import alert for certain foreign-made temporary tattoos (http://www.accessdata.fda.gov/cms_ia/importalert_133.html)** containing colors that are not permitted for this use or don't carry the FDA-mandated list of ingredients. Additionally, FDA has received reports of allergic reactions to temporary tattoos.

In a similar action, FDA has issued an **import alert for henna intended for use on the skin (http://www.accessdata.fda.gov/cms_ia/importalert_138.html)**. Henna is approved only for use as a hair dye, not for direct application to the skin. Also, henna typically produces a reddish brown tint, raising questions about what ingredients are added to produce the varieties of colors labeled as "henna," such as "black henna" and "blue henna." Hair dyes are not approved for use on the skin, and some people may be sensitive to them. FDA has also received reports of allergic reactions to temporary tattoos that contain henna and those consisting only of hair dye. Some reactions have resulted in scarring.

To learn more, see **Temporary Tattoos, Henna/Mehndi, and "Black Henna." (/Cosmetics/ProductsIngredients/Products/ucm108569.htm)**

Reporting Adverse Reactions

FDA urges consumers and healthcare providers to report adverse reactions from tattoos, permanent makeup, and temporary tattoos, as well as problems with tattoo removal.

Consumers and healthcare providers can report problems to **MedWatch (http://www.fda.gov/Safety/MedWatch/default.htm)**, FDA's problem-reporting program, on the Web or at 1-800-332-1088; or by contacting the nearest FDA **consumer complaint coordinator (http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm)**.

For more information, see the additional resources listed under **Tattoos and Permanent Makeup (/Cosmetics/ProductsIngredients/Products/ucm107327.htm)**.

*For related information on infections from tattooing, see the following documents from the Centers for Disease Control: **Viral Hepatitis B Fact Sheet (http://www.cdc.gov/ncidod/diseases/hepatitis/b/fact.htm)** and **"Methicillin-Resistant *Staphylococcus aureus* Skin Infections Among Tattoo Recipients --- Ohio, Kentucky, and Vermont, 2004-2005" (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5524a3.htm)** (published in *Morbidity and Mortality Weekly Report*, June 23, 2006).

November 29, 2000; updated June 23, 2008, February 1, 2010, and August 22, 2012. This information is current. It is updated only when necessary.

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Resources for You

- Tattoo Inks Pose Health Risks–Consumer Update (/ForConsumers/ConsumerUpdates/ucm316357.htm)
- Tattoo Ink-Related Infections–Awareness, Diagnosis, Reporting, and Prevention (http://www.nejm.org/doi/full/10.1056/NEJMp1206063) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Think Before You Ink: Are Tattoos Safe?–Consumer Update (/ForConsumers/ConsumerUpdates/ucm048919.htm)
- Bad Reaction to Cosmetics? Tell FDA–Consumer Update and Video (/ForConsumers/ConsumerUpdates/ucm241820.htm)
- Tattoos and Permanent Makeup: Marketplace and Chemistry–Webinar (http://learningcenter.nsta.org/products/symposia_seminars/fall09/fda/webseminar4.aspx) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)
- Temporary Tattoos, Henna/Mehndi, and "Black Henna": Fact Sheet (/Cosmetics/ProductsIngredients/Products/ucm108569.htm)
- Import Alert #53-14: Intensified Coverage of Temporary Tattoos Containing Non-Permitted Color Additives and/or Failing to Bear Ingredient Declaration (http://www.accessdata.fda.gov/cms_ia/importalert_133.html)
- Import Alert #53-19: Detention Without Physical Examination of Henna Based Skin Color (http://www.accessdata.fda.gov/cms_ia/importalert_138.html)

More in Products (/Cosmetics/ProductsIngredients/Products/default.htm)

Aromatherapy (/Cosmetics/ProductsIngredients/Products/ucm127054.htm)

Disposable Wipes (/Cosmetics/ProductsIngredients/Products/ucm441465.htm)

Hair Products (/Cosmetics/ProductsIngredients/Products/ucm127988.htm)

Makeup (/Cosmetics/ProductsIngredients/Products/ucm134054.htm)

Nail Care Products (/Cosmetics/ProductsIngredients/Products/ucm127068.htm)

Soaps & Lotions (/Cosmetics/ProductsIngredients/Products/ucm388824.htm)

Tanning Products (/Cosmetics/ProductsIngredients/Products/ucm134059.htm)

Tattoos & Permanent Makeup: Guide to Resources (/Cosmetics/ProductsIngredients/Products/ucm107327.htm)

Gemdo Cosmetics, Inc. 4/16/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

UNITED PARCEL SERVICE
SIGNATURE REQUIRED

April 16, 2015

WL # 16-15

Patricia Alvarez, President
Gemdo Cosmetics Inc.
29151 Ave. Penn
Valencia, CA 91355-5441

Dear Mrs. Alvarez:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your contract cosmetic manufacturing facility located at 29151 Ave. Penn, Valencia, California, on December 8, 2014 through December 23, 2014 in response to a Class II Recall of Juice Beauty Illuminating Eye Shadow products (chocolate, cappuccino, and champagne shades), manufactured at your facility, that were found to be contaminated with the ocular pathogen, *Bacillus cereus*. In addition, during our inspection we also inspected your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321 *et seq.*]. Your firm is a contract manufacturer for various products, including Juice Beauty, Inc. The products you manufacture, pack and label are intended to be applied to the human body for beautifying, promoting attractiveness, or altering the appearance, and as such, they are cosmetics within the meaning of section 201(i) of the Act [21 U.S.C. 321(i)]. The microbial contamination of the Juice Beauty Illuminating Eye Shadow products causes these products to be adulterated within the meaning of section 601(a) of the Act [21 U.S.C. 361(a)], as described further below. Furthermore, the conditions observed during the inspection cause Juice Beauty Illuminating Eye Shadow products and other eye area products manufactured in the dry room to be adulterated within the meaning of section 601(c) of the Act [21 U.S.C. 361(c)], as described further below. It is a violation of Section 301(a) of the Act [21 U.S.C. 331(a)] to introduce or deliver for introduction into interstate commerce an adulterated cosmetic. You may find the Act and its implementing regulations through links on FDA's home page at **http://www.fda.gov (http://www.fda.gov/)**.

Under section 601(a) of the Act [21 U.S.C. 361(a)], a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Juice Beauty Illuminating Eye Shadow (chocolate, cappuccino, and champagne shades) products manufactured at your facility are adulterated under section 601(a) of the Act in that they were found by FDA laboratory analysis to contain the ocular pathogen, *Bacillus cereus* which may render the products injurious to health. Bacillus species are Gram-positive rod-shaped bacteria that are widely found in the environment, such as soil, dust, water, and sediments. Their spores are resistant to desiccation and heat, and therefore are able to survive the manufacturing process. Vegetative cells produce a range of toxic enzymes responsible for tissue destruction and reactivity.

Particularly, *Bacillus cereus* contaminated eye-area products may cause users to develop bacterial conjunctivitis, keratitis and periorbital cellulitis. In particular, this pathogen can cause a rapidly progressive endophthalmitis (i.e., inflammation of the intraocular cavities or the aqueous and/or vitreous humor of the eye) that is resistant to treatment. Significant loss of vision, and often loss of the eye itself, can occur within 24 to 48 hours after exposure to *B cereus*.

Additionally, Juice Beauty Inc. Illuminating Eye Shadow products are formulated with preservative systems other than the preservative systems listed under Appendix C of FDA Compliance Program Guidance 7329.001 (available at **http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM208412.pdf (http://www.fda.gov/downloads/Cosmetics/GuidanceRegulation/GuidanceDocuments/UCM208412.pdf)**). Cosmetics need not be aseptic, however, they must not be contaminated with microorganisms which may be pathogenic, and the density of non-pathogenic microorganisms should be low (see FDA's Bacteriological Analytical Manual (BAM), "Chapter 23: Microbiological Methods for Cosmetics," Section C-Interpretation *available at* **http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm073598.htm)**). It appears that adequate testing was not performed, as your firm could not provide the documents for FDA review. FDA notes that quality control testing of incoming materials is a fundamental part of cosmetic good manufacturing

practices and solely relying on certificates of analysis from a vendor is not advised by the Agency. Dry powders and raw materials of natural origin used in shaded and eye area cosmetics are likely to carry high numbers of *B. cereus* spore forming organisms. Botanical, organic and inorganic raw ingredients are especially vulnerable to microbial contamination and should be afforded increased scrutiny by cosmetic manufacturers prior to their use.

Under Section 601(c) of the Act [21 U.S.C. 361(c)], a cosmetic is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Insanitary conditions were observed during our December 8, 2014 through December 23, 2014 inspection that cause the Juice Beauty Illuminating Eye Shadow products and the other products manufactured in the production area where the Juice Beauty eye shadow products were manufactured to be adulterated. Specifically, environmental samples taken from the production area on and around **(b)(4)** and **(b)(4)** in the dry room were found contaminated with *Bacillus cereus*. These findings suggest insanitary conditions and that the work environment was supporting the growth of *B. cereus*. The findings also suggest that manufacturing operation or conditions at this facility may be operated in a manner which is likely to, or may have contributed to the contamination and adulteration of the eye area and other cosmetic products processed in the dry room. The growth and presence of *B. cereus* in the dry room could be caused by a failure to properly clean and sanitize. This includes a disinfection regime that disinfects, kills or inactivates spores. Bacillus endospores in particular are resistant to hostile physical and chemical conditions; this means that they can be difficult to remove without an effective sanitization regime. FDA noteseffective monitoring and sanitation controls for cosmetic products and control of the processing environment is important to controlling microbiological growth in cosmetic products.

In addition, our inspection revealed insanitary practices that may lead to insanitary conditions that may cause your products to become contaminated with filth or rendered injurious to health. Specifically, we observed that:

- The microbial safety of raw materials is not routinely evaluated in that materials are not sampled and tested or examined in conformance with specifications that could ensure the absence of contamination with filth, microorganisims or other adulterants to the extent necessary to prevent adulteration of finished products. In particular, you stated to our inspector that you do not routinely test incoming lots of raw materials used in the manufacture of cosmetic products prior to their use, in order to confirm suitability. Sufficient controls are necessary to ensure that materials are of suitable cleanliness prior to entry into the cosmetic processing area to prevent product contamination.
- You do not routinely review raw material records, including records of origin, receipt, examination, testing, disposition, and use, to determine if raw material is adequately controlled. In particular, you do not have written quality control measures for the raw materials used to manufacture cosmetics at your facility and our inspector observed that the following ingredients, which may have been used in the manufacture of cosmetic products in your facility were past their recommended use dates: **(b)(4)**. Although you indicated that the vendor's certificates of analysis of raw materials demonstrated quality control measures, we recommend that you review raw material records and establish written procedures that help to better control the examination, testing, disposition, and use of raw materials.

Accordingly, the Juice Beauty Eye Shadow products and the other eye area products manufactured in the same production room as Juice Beauty Eye Shadow are adulterated within the meaning of section 601(c) of the Act. We note that, in our Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for cosmetics, we recommend a number of guidelines for effective self-inspection that may assist cosmetic manufacturers to minimize the risk of adulteration. These guidelines are available at
http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm (http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm).

We also note that contaminated Juice Beauty Illuminating Eye Shadow (chocolate, cappuccino, and champagne shades) products were recalled in August 2014. Because of the contamination in your facility, we recommend that you implement quality controls and/or reconditioning processes to ensure the safety of the products you manufacture. Additionally, we recommend that you develop a remediation plan to correct and prevent future product contamination caused by use of contaminated raw materials and subsequently provide for the safe distribution of these products.

This letter is not an all-inclusive list of violations at your facility. It is your responsibility to ensure that all products manufactured, processed, and packed by your firm comply with the Act and its implementing regulations. We advise you to develop a plan for preventing the recurrence of these violations or the occurrence of other violations. We request that you take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in enforcement action, seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. You should include in your response any documentation or other useful information that would assist us in evaluating your corrections. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented.

If you have any questions about this letter, please contact Compliance Officer at (949) 608-2918 or **Raymond.Brullo@fda.hhs.gov (mailto:Raymond.Brullo@fda.hhs.gov)**.

Your response should be sent to:

CAPT Daniel Cline, Acting Director
Compliance Branch, Los Angeles District
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,
/S/
Alonza E. Cruse, Director
Los Angeles District

Cc:
David M. Mazzera, Chief, Food and Drug Branch
California Department of Public Health
PO Box 997435
1500 Capitol Ave., MS-7602
Sacramento, CA 95899-7413

More in 2015
(/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

Inspections, Compliance, Enforcement, and Criminal Investigations

Vienna Beauty Products 5/17/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

May 17, 2012

WARNING LETTER
CIN-12-269898-16

Via United Parcel Service

Mr. Timothy K. Miller, President
Vienna Beauty Products
347 Leo Street
Dayton, Ohio 45404

Dear Mr. Miller:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your cosmetic manufacturing facility located at 347 Leo Street, Dayton, OH on October 17-18, 25, November 7, and December 22, 2011 to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Your Triple Lanolin Aloe Vera Foot Scrub is intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and as such, it is a cosmetic within the meaning of section 201(i) of the Act [21 U.S.C. 321(i)]. During the inspection, our investigators observed and documented insanitary conditions. An analysis of your Triple Lanolin Aloe Vera Foot Scrub collected durin the inspection found significant microbial contamination. The microbial contamination of the product, in conjunction with the conditions observed during the inspection, causes your Triple Lanolin Aloe Vera Foot Scrub to be adulterated within the meaning of Sections 601(a) and (c) of the Act [21 U.S.C. 361(a) and (c)]. It is a violation of Section 301(a) of the Act [21 USC 331(a)] to introduce or deliver for introduction into interstate commerce any cosmetic that is adulterated or misbranded. You may find the Act and its implementing regulations through links on FDA's home page at http://www.fda.gov[1].

Under Section 601(a) of the Act [21 U.S.C. 361(a)], a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. Your Triple Lanolin Aloe Vera Foot Scrub is adulterated in that it bears or contains an excessive level of microorganisms as evidenced by high Aerobic Plate Counts (APC), which may render it injurious to health. APC measures the level of microorganisms in a product and can indicate the quality of the product. Cosmetics must be free of high-virulence microbial pathogens and the total number of aerobic microorganisms per gram must be low. FDA has established a guideline for non-eye area products in which the APC should not be greater than 1000 CFU/g. FDA analysis of your Triple Lanolin Aloe Vera Foot

Scrub determined that Composite sample 1 contained 150,000 APC/g and Composite sample 2 contained 98,000 APC/g. Of particular concern, the pathogens Pseudomonas aeruginosa and Burkholderia multivorans/B. cepacia group were identified in the product. Many of these bacteria are widespread in th environment and may be introduced into a cosmetic manufacturing facility from raw materials, water and equipment.

Under Section 601(c) of the Act [21 U.S.C. 361(c)], a cosmetic is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Insanitary conditions were observed during our inspection that causes your Triple Lanolin Aloe Vera Foot Scrub product to be adulterated. Specifically, there was apparent filth and dust build up on manufacturing equipment in the production area. A layer of sediment and encrusted material was observed on the exterior and tops of production kettles in use. Information obtained during the inspection indicates that the production room floor is cleaned and sanitized once per year; the last cleaning was performed November 2010 during a shutdown period. Base on other information obtained during the inspection, the 250 and 500 gallon kettles were last cleaned 15 years ago. The last cleaning of the 400 gallon shower gel kettle could not be determined. Additionally, the finished product storage tank and storage totes were said to have last been cleaned over 20 years ago.

During the inspection several insanitary practices were observed that have the potential to cause your product to be contaminated with filth or become injurious to health. For Example:

1. The microbial safety of starting materials does not appear to be routinely evaluated. Materials ar not sampled and tested or examined in conformance with procedures assuring the absence of contamination with filth, microorganisms or other extraneous substances to the extent necessary to prevent adulteration of finished products.

2. Fixtures, ducts and pipes are not installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk. The FDA investigator was advised that during summer month's condensation may form on piping above manufacturing kettles which may subsequently drip into kettles. This conditio may result in microbial contamination of the product.

3. Failure to regularly test water used as a cosmetic ingredient to assure chemical and microbiological quality. Routine testing of the water supply used in the facility to formulate cosmetics and clean equipment and manufacturing areas should be conducted to assure that it is no a source of contamination.

4. Production area and the equipment for processing, transfer and filling equipment and the containers for holding raw and bulk materials are not well maintained, cleaned and sanitized at appropriate intervals.

5. Raw materials and primary packaging materials are not stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture. Specifically, the investigator observed one 50 lb bag of Cetyl Alcohol, Lot 1698110315FAL-T23 stored directly on the production floor. Cetyl Alcohol is used in all of the firm's lotion products.

6. Manufacturing controls have not been established, and written instructions, i.e., formulations, processing, transfer and filling instructions, in-process control methods etc., are not being maintained.

7. Samples of cosmetic products are not taken, as appropriate, during and/or after processing, transfer or filling to determine adherence to internal quality standards and absence of hazardous microorganisms or chemical contaminants. The FDA investigator was advised that in 2007 your firn ceased microbial testing of all labeled products. Your plant manager provided documentation that from 2000 to present at least 22 occasions of microbial contamination of the finished product occurred. Your firm did not identify the cause of the microbial contamination.

8. There is a failure to maintain complete control records of raw materials, primary packaging materials, batch and quality control records. Batch and quality control records should include (1) kinds, lots and quantities of material used; (2) processing, handling, transferring, holding and filling records; (3) sampling, controlling, adjusting and reworking recodes and (4) code marks of batches and finished products.

We acknowledge the receipt of your response dated November 9, 2011. However, we find your response

to be inadequate in that you did not provide any detailed information regarding proposed corrective actions that the firm plans to take.

This letter may not list all the violations at your facility. You are responsible for investigating and determining the causes of the violation identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility as a manufacturer to ensure that the products you firm markets are safe and otherwise in compliance with all applicable legal and regulatory requirements.

You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action without further notice, including but not limited to, seizure and/or injunction. You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed.

Your written response should be sent to Allison C. Hunter, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237. If you have any questions about this letter, please contact Compliance Officer Hunter at 513-679-2700 Ext. 2134.

Sincerely yours,

/s/

Paul J. Teitell
District Director
Cincinnati District Office

Inspections, Compliance, Enforcement, and Criminal Investigations

Carrington Laboratories, Inc 05-Dec-05

Department of Health and Human Services

Public Health Service
Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 5, 2005

2006-DAL-WL-09

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Carlton E. Turner, Ph .D ., D .Sc:
President and CEO
Carrington Laboratories, Inc.
2001 Walnut Hill Lane
Irving, TX 75038

Dear Dr. Turner:

On August 24-30, 2005, an investigator from the Dallas District Office of the Food and Drug Administratior (FDA) inspected your firm, located at 2001 Walnut Hill Lane, Irving, Texas. During this inspection, sample were collected for analytical testing and for a detemination regarding compliance with the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act on FDA's web site at www.fda.gov.[1]

Our analysis found the presence of the microorganism *Burkholderia cepacia* in lots 0505851 and 0505832 of your Medline Alcohol-Free Mouthwash (4 fl. oz.) products. These products, therefore, were adulterated within the meaning of section 601(a) of the Act [21 U.S.C. § 361(a)], in that they bore or contained a poisonous or deleterious substance which may have rendered them injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual.

Additionally, we found that your Medline Alcohol-Free Mouthwash products (2 fl. oz. and 4 fl. oz.) were adulterated within the meaning of section 601(c) of the Act [21 U.S.C. § 361(c)], in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Your employees failed to follow appropriate procedures for sanitizing the equipment filling hoses, which, according to your investigation, were found to be contaminated with *B. cepacia*. At least 10 lots of finished product were distributed that were later determined to have been contaminated with *B. cepacia.*

Some of these mouthwash products were also misbranded within the meaning of section 602(a) of the Act [21 U.S.C. § 362(a)], because their labels failed to declare a color additive ingredient properly. Review of your production records for these products reveals that they are formulated with FD&C Blue No. 1. Title 21, *Code of Federal Regulations* (CFR), Section 701.3 requires that this color additive be declared as an

ingredient as "FD&C Blue No. 1" or "Blue 1." However, the labels for some of your products simply listed "Blue Dye" as an ingredient.

The above observations are not intended to be an all-inclusive list of violations. It is your responsibility tc ensure adherence with all requirements of the Act. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction. We note that you initiated a recall of all codes of your Medline Alcohol-Free Mouthwash. We also note that you submitted a response to the Inspection Observations Form FDA-483 issued to you at the end of this inspection, which did not address Observation 2 . We received another response letter dated November 17, 2005. In this letter, Observation 2 is still not addressed and no additional information was provided in response to Observation 3.

Please notify this office in writing within 15 working days of receipt of this letter, the additional specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include documentation of any additional investigation conducted to determine the underlying cause of the contamination of the equipment or your products.

Your response should be sent to Sherrie L. Krolczyk, Compliance Officer at the above letterhead address. If you have questions regarding any issue in this letter, please contact Ms. Krolczyk, at 214/253-5312.

Sincerely,

/S/

Michael A: Chappell
Dallas District Director.

Inspections, Compliance, Enforcement, and Criminal Investigations

The Master's Miracle, Inc. 09-Jun-05

Department of Health and Human Services

Public Health Service
Food and Drug
Administration

Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 768-7114
FAX: 4612) 334-4142

June 9, 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05-14

Michael Schlegel
CEO/Director of Marketing
The Master's Miracle, Inc.
9060 Zachary Lane North, Suite 104
Maple Grove, MN 55369

Dear Mr. Schlegel:

This letter is in reference to your firm's manufacturing, distribution, and promotion of various products documented by our inspection conducted December 28-30, 2004, and January 5-6, 11, 13 and 24, 2005, at your facility located at 9060 Zachary Lane North, Suite 104, Maple Grove, Minnesota, and by a review of your Internet website at *www.themastersmiracle.com*. These activities were conducted to determine your firm's compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and applicable implementing regulations contained within Title 21, Code of Federal Regulations (21 CFR).

Our review of your products, labeling, and promotional materials reveals serious violations of the Act. You can find the Act and implementing regulations through links on FDA's Internet home page at www.fda.gov.[1]

Adulterated Cosmetic Charge

FDA conducted an analysis of a sample of your Skin Moisturizer product collected during the inspection. This analysis revealed bacterial contamination and aerobic plate counts at levels that pose a potential health risk for the uses recommended in your labeling. Your product is therefore adulterated under section 601(a) of the Act because it contains a poisonous or deleterious substance that may render the product injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual [21 U.S.C. 361(a)].

Drug Charges

Under the Act, articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man are drugs [section 201(g)(1)(B) of the Act, 21 U.S.C. 321(g)(i)(B)]. Promotional materials that accompany your products in interstate commerce, label claims, and claims on your website and in your promotional audiocassettes show that your products are intended for use in the cure, mitigation, treatment or prevention of disease.

Examples of disease prevention and treatment claims for NatureRich™ Greens product in your Master's Miracle Product Guide and brochure entitled "Give Your Body the Richness of Nature" are as follows:

- "Nutritional deficiencies may play a major role in health problems such as heart disease, cancer, diabetes and obesity. . . . The Master's Miracle NatureRich™ Greens provide power-packed super foods. ..to nourish the body."
- "Disease and pain flourish in an acidic environment. A balanced pH provides the best environment tc assimilate nutrients in the body and enhance the body's healing ability . ..naturally. NatureRich™ Greens is a special formulation of greens that help promote a balanced pH. . . .".

Examples of disease prevention and treatment claims for your Flax Hull Lignans product in the Miracle of Flax Hull Lignans booklet, the Master's Miracle product guide, and the immediate product label are as follows:

"Help the body combat disease by fortifying the immune system with Flax Hull Lignans. . . . The end resu is a potent antioxidant that . . .has antiviral, antibacterial and antifungal properties. Historically, studies have shown that lignans may help prevent the three leading major illnesses in the U.S. heart disease, cancer and diabetes."

- "[L]ignans . . .may interfere with the development of breast, prostate, colon, and other cancers . . . . These lignan compounds have-been studied . . . for their cancer preventative properties. The SDG lignan not only has anticancer properties, it also has anti-viral, anti-bacterial, and anti-fungal properties. . . . Studies indicate that people who eat more lignan-containing foods have a lower incidence of breast and colon cancer, due to the phytoestrogen effect."
- "[L]ignans reduce estrogen's effects by displacing it from cells. This displacement of the hormone can help prevent those cancers, such as breast cancer, that depend on estrogen to start and develop . .. .SDG is beneficial throughout the promotional phase of carcinogenesis, and at the stage when tumors have already been established . . .lignans taken during early postnatal life may reduce the risk of developing breast cancer."
- "SDG is particularly effective in combating cancer of the colon."
- "[F]laxseed ingestion produced anticarcinogenic lignans in the colon."
- "[F]laxseed decreases the risk for colon carcinogenesis ."
- "[C]onsumption of flaxseed and its lignans may reduce the risk for colon carcinogenesis ."
- "[O]ver the long term flaxseed lignan still exerts a colon cancer protective effect."
- "[L]ignans are growth inhibitors of colon tumor cells and may act through mechanisms other than anti-estrogenic activity."
- "[L]ignan SDG. . .can help prevent or significantly delay the development of diabetes."
- "SDG reduced the development of adult-onset (type 2) diabetes by 80 percent, and delays the development of the disease significantly."
- "SDG reduced the development of the type 1 diabetes by 71 and 75 percent respectively."
- "It is well known that flax oil fights heart disease by lowering dangerous LDL cholesterol and trigiycerides, and reducing the build up of atherosclerotic plaque on artery walls. But now, evidence is revealing that SDG lignan . . .has an equal or greater effect in fighting heart disease."
- "[A]ddition of SDG resulted in a 73% reduction in atherosclerotic plaques (fatty deposits) . . . . [T]here was a 33% reduction in serum cholesterol and an increase in the "good" or protective

cholesterol in SDG-fed rabbits."

- "SDG is effective in reducing hypercholesterolemic atherosclerosis. . . ."
- "The ability of SDG in reducing atherosclerosis is partly due to its antioxidant activity."
- "[T]he reduction of hypercholesterolemic atherosclerosis is greater with SDG than with the whole flaxseed. The decrease is associated with a reduction of serum cholesterol and LDL-cholesterol."
- "In a study of 29 hyperlipidemic subjects who were placed on a diet of 50 grams of partially defatte flaxseed, their LDL cholesterol was reduced 7.6% after only three weeks."
- "[F]lax lignan ha[s] a beneficial role in chronic renal (kidney) disease."
- "[C]onsumption of flaxseed rich in lignans retards the development and progression of chronic renal disease."
- "[L]ignans in flaxseed improve kidney function in certain types of kidney diseases. . . . [I]t preserved renal function and reduced histological injury."
- "[F]laxseed was beneficial in slowing the decline in renal function ."
- "SDG has a therapeutic role in animal and human lupus nephritis. It is known that in patients with lupus nephritis . ..there is an increase in the production of platelet activating factors (PAF) . . . . Lignans acts as PAF receptor antagonists which means the lignans reduce the accumulation PAFs [sic] . . . . PAF-induced platelet aggregation was inhibited by all doses . . . . In conclusion, the flaxseed conferred significant benefits in reducing inflammatory and atherogenic mechanisms important in the pathogenesis of lupus nephritis."
- "Prostate Cancer. . . Flaxseed ingestion produces large amounts of mammalian lignans with weak estrogenic/anti-estrogenic properties. In tests, these properties reduced adult relative prostate weight and cell proliferation, suggesting potential protection against prostatic disease .. .."
- "[B)oth isoflavonoids and lignans are natural cancer protective compounds and are useful against skin cancer."
- "Flax reduced tumor occurrence by up to 63%."
- "The addition of flaxseed to the diet also caused a dose-dependent decrease on tumor area and volume, showing that it could be beneficial in both prevention and treatment."
- "Further, the rich source of lignans reduced metastasis (the spread of cancerous cells) and inhibited the growth of the metastatic secondary tumors. . . ."
- "[L]ignans . ..can help prevent breast cancer."
- "Controlling menstrual cycles has several health benefits including decreasing the risk of breast cancer. Lignans in flaxseed have been shown to regulate women's menstrual cycles."
- "The control which lignan has over the menstrual cycle has an influence on cancer growth. This is because the less time a woman spends in the luteal phase, the lower the risk of breast cancer."
- "[L]ignans are anti-parasitic."
- "Dietary supplementation with SDG, the lignan from flaxseed, significantly reduced pulmonary metastasis of melanoma cells and inhibited the growth of metastatic tumors that formed in the lungs. This may aid in the fight against lung cancer."
- "Flaxseed and its lignan have been shown to reduce inflammatory responses, but it did not prevent macrophages (cells of the immune system) from killing bacteria. The research . . .involving lupus revealed that lignans are beneficial for reducing inflammation."
- " (Product label) "Researchers have studied its effects on hormone related tumors. . . and heart disease."

These claims cause your Nature Rich™ Green and Flax Hull Lignans products to be drugs, as define

in section 201(g)(1) (B) of the Act [21 U.S.C. 321(g)(1)(B)]. Because these products are not generally recognized as safe and effective when used as labeled, they are also new drugs as defined in section 201(p) of the Act [21 U.S.C. 321(p)]. Under section 505 of the Act [21 U.S.C 355], a new drug may not be legally marketed in the United States without an approved New Drug Application (NDA) FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective. Further, these products are misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C 352(f)(1)].

In addition to the claims cited above, your website at *www.themasterrniracle.*comm and audio promotional materials further show the intended use of your products.

Examples of disease prevention and treatment claims on your website are as follows:

- "Flax Hull Lignans . . .may help prevent three major diseases-heart disease, cancer and diabetes."
- "Help the body combat disease by fortifying the immune system with Flax Hull Lignans ."
- " Your website lists the following about acid levels in the body:

  o "Dozens of diseases have a hidden link to excessive acid in the body, contributing to. . .chronic pain and fatigue."

  o "Dozens of health conditions, including asthma, chronic tiredness, depression. . . are present due to an acidic environment.. . . Even serious health conditions such as cancer, autoimmune diseases .. .are - linked to extremely acidic levels . . . ."

  o Another page describing the Fortified Mineral Neutralizer states "Disease [sic] and pain flourish in an acidic environment. A balanced pH provides the best environment to assimilate nutrients in the body and enhance the body's healing ability. . .naturally. The energy and essential minerals in the Fortified Mineral Neutralizer can be beneficial in helping with balancing the body's pH." Taken together, these statements imply that the Fortified Mineral Neutralizer can treat the preceding diseases associated with high acid levels.

Examples of disease treatment and prevention claims from one of your audio cassettes entitled "The Master's Miracle Product and Opportunity Testimonials" are
as follows:

- "I've suffered from Chronic Fatigue Syndrome and fibromyalgia. .. and [Master's Miracle products are] the answer that people have been looking for for a long time."
- "Well, Master's Miracle products gave my life back. I had a couple bouts with pneumonia. Later, I was diagnosed with emphysema. I was on oxygen 24 hours a day. And three weeks on this product, no daytime oxygen ."

These claims are further evidence that your Master's Miracle products are drugs as defined in section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)], in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. These products are misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C 352(f)(1)].

Unsubstantiated Structure/Function Claims

In addition, the labeling of your Master's Miracle products bears claims regarding the products' effect on the structure and function of the body (structure/ function claims). Examples of such claims are as follows:

- Product Guide:

  o "The Master's Miracle Natural Simple Solution System can help. . . balance the pH of the body.. . .

- " Give Your Body the Richness of Nature brochure:

  o "NatureRich™ Greens Promotes a balanced chemistry/ pH. . . ."
  o "Nature's Rich Greens is a special formulation of greens that-help, promote a balanced pH.. . ."

- " Would You Sacrifice Your Health For Bubbles? Brochure:

  o "Discover how using our products help to. . .balance the body's pH."

- " Training Guide:

  o "This `pH Pack' includes The Master's Miracle Neutralizer. . . that help neutralize acids in your body."
  o "The Fortified Mineral Neutralizer can be beneficial in helping with balancing the body's pH."

We have reviewed these claims and have concluded that they are not supported by competent and reliabl scientific evidence. Because these claims lack substantiation, they are false and misleading, and cause your Master's Miracle products to be misbranded within the meaning of section 403(a)(1) and 403(r)(6)(B of the Act [21 U.S.C 343(a)(1) and (r)(6)(13)].

Other Labeling Violations

Even if your Ultra Fortified Mineral Neutralizer and Fortified Mineral Neutralizer were not drugs, as dietar supplements they would be misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. 343(q)(5)(F)) in that the products' labels do not include a Supplement Facts panel as required by 21 CFR 101.36.

Even if your Flax Hull Lignans were not a drug, as a food it would be misbranded within the meaning of section 403(q)(1) of the Act [21 U.S.C. 343(q)(1)] in that the product is labeled with a Nutrition Facts panel that is not in the format required by 21 CFR 101.9. We also note that you labeled your product as a "food supplement," and included the dietary supplement disclaimer under section 403(r)(6) of the Act. However, these statements are not consistent with other labeling representing your product as a conventional food (e.g., Nutrition Facts panel rather than Supplement Facts panel, suggested uses as a salad or cereal topping). A product that is represented as a conventional food is not a dietary supplement (see section 201(ff)(2)(B) of the Act [21 U.S.C. 321(ff)(2](B)].

Even if your Nature Rich™ Greens were not a drug, as a dietary supplement it would be misbranded within the meaning of section 403(q)(5)(F) of the Act [21 U.S.C. 343(q)(5)(F)] in that the product is labeled with a Supplement Facts panel that is not in the format required under 21 CFR 101.36.

As a dietary supplement, your Nature Rich™ Greens is also misbranded under section 403(r)(1)(A) c the Act [21 U.S.C. 343(r)(1)(A)] because the product labeling bears a nutrient content claim but the product does not comply with the regulation that would allow it to bear such a claim. When used to describe the level of a nutrient, the term "rich in" is defined by regulation to mean that the product contains 20% or more of the Daily Reference Value (DRV) or Recommended Daily Intake (RDI) of that nutrient per reference amount customarily consumed [21 CFR 101.54(b)(1)]. The labeling of your product in the Product Guide bears the claim, "rich. . . in fiber;" however, the product is labeled to contain less than 20% of the DRV for fiber per serving.

This letter is not intended to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that all products distributed by your firm are in compliance with the Act and its implementing regulations.

During the inspection, we collected samples of the Fortified Mineral Neutralizer and Ultra Fortified Mineral Neutralizer products. FDA analysis of these products revealed significant bacterial contamination and aerobic plate counts. You were advised of the results of our analysis by telephone on February 24, 2005. You should be aware that consumption of these products may pose a public heath risk. On May 13, 2005, you responded in a letter sent via e-mail to Compliance Officer Tyra Wisecup at the FDA's Minneapolis District Office in part that the results of the FDA analysis for the product tested present no health hazards as opined by the microbiologists from the firm, **[redacted]** that you hired. You also indicated that you intend to implement "product testing" and hire engineers to address your water systems. Please also be aware that FDA's Center for Drug Evaluation and Research is currently evaluating the safety of these Mineral Neutralizer products for topical use.

We request that you take prompt action to correct the violations listed above. Failure to promptly correct these violations may result in enforcement action being initiated by FDA without further notice. The Act provides for the seizure of illegal products and/or injunction against the manufacturers and distributors of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the letterhead.

Sincerely,

/S/

W. Charles Becoat
Director
Minneapolis District

Page Last Updated: 07/08/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Tattoo-Associated Nontuberculous Mycobacterial Skin Infections — Multiple States, 2011–2012

On August 22, this report was posted as an MMWR *Early Release on the* MMWR *website (http://www.cdc.gov/mmwr).*

Permanent tattoos have become increasingly common, with 21% of adults in the United States reporting having at least one tattoo (*1*). On rare occasions, outbreaks of nontuberculous mycobacterial (NTM) skin infections have been reported after tattooing (*2,3*). In January 2012, public health officials in New York received reports of *Mycobacterium chelonae* skin infections in 14 New York residents who received tattoos during September–December 2011. All infections were associated with use of the same nationally distributed, prediluted gray ink manufactured by company A. CDC disseminated an Epi-X public health alert to identify additional tattoo-associated NTM skin infections; previously identified cases were reported from three states (Washington, Iowa, and Colorado). Public health investigations by CDC, state and local health departments, and the Food and Drug Administration (FDA) found NTM contamination in tattoo inks used in two of five identified clusters. All infected persons were exposed to one of four different brands of ink. NTM contamination of inks can occur during the manufacturing process as a result of using contaminated ingredients or poor manufacturing practices, or when inks are diluted with nonsterile water by tattoo artists. No specific FDA regulatory requirement explicitly provides that tattoo inks must be sterile. However, CDC recommends that ink manufacturers ensure ink is sterile and that tattoo artists avoid contamination of ink through dilution with nonsterile water. Consumers also should be aware of the health risks associated with getting an intradermal tattoo.

On January 4, 2012, the Monroe County (New York) Department of Public Health began an outbreak investigation after receiving a report of a person with a persistent papular rash beginning 1 week after being tattooed by an artist in October 2011; *M. chelonae* was isolated from a skin biopsy. Since May 2011, the artist had been using company A prediluted gray ink. Using a list of customers provided by the artist, a total of 19 infections were identified, including 14 confirmed with *M. chelonae*.

All infected persons had been tattooed with company A prediluted gray ink. The tattoo artist said he had not diluted the ink before use, and a review of his practices did not reveal other potential sources of contamination. *M. chelonae* was isolated from tissue specimens, and from one opened and one unopened bottle of company A prediluted gray ink. Pulsed-field gel electrophoresis (PFGE) patterns of 11 available patient isolates and an unopened bottle of company A prediluted gray ink were indistinguishable; the *M. chelonae* isolate from the opened ink bottle showed ≥95% genetic relatedness to the other isolates. Water and environmental samples collected at the manufacturing company and tattoo parlor were negative for *M. chelonae*.

Company A prediluted gray ink was a nationally distributed product. To identify additional tattoo-related NTM infections not limited to exposure to any particular brand of ink, case finding was initiated February 15, 2012, through Epi-X using the following case definitions: 1) a *possible case* was defined as persistent inflammatory reaction (i.e., redness, swelling, or nodules) localized within the margins of a new tattoo on a person between May 1, 2011, and February 10, 2012; 2) a *probable case* was defined as a possible case with evidence of an NTM infection by histopathology or clinical response to treatment; 3) a *confirmed case* was defined as a possible case with NTM cultured from a wound or skin biopsy. The New York cluster included 14 confirmed and four probable cases, and one possible case. An investigation by Public Health – Seattle & King County, Washington, identified five confirmed and 26 possible cases. Confirmed cases also were reported from Iowa (two) and Colorado (one) (Table). Among 22 confirmed cases, 63.6% involved men, and the median age of persons in the 22 cases was 33.5 years (range: 20–48 years).

Cases identified in Washington were associated with two clusters, and the initial two cases from patients with recent tattoos were reported by clinicians to local public health authorities. The first, Washington cluster 1, had three confirmed *Mycobacterium abscessus* cases and 24 possible cases in persons tattooed with black ink from company B. Water and environmental samples collected from company B did not grow NTM, but the company reported receiving complaints of unusually long-lasting skin reactions in clients tattooed with company B black ink from 35 customers in 19 states between August 2011 and March 2012. Customer identifiers were not available to CDC for follow-up. Two *M. abscessus* clinical isolates from Washington cluster 1 were indistinguishable by PFGE, but NTM was not recovered from samples of brand B ink. The second Washington cluster had two confirmed cases of *M. chelonae* and two possible cases associated with company C gray ink. One clinical isolate from Washington

TABLE. Characteristics of nontuberculous mycobacteria (NTM) tattoo-associated skin infection clusters — multiple states, 2011–2012

State	No. of cases			*Mycobacterium* species identified	Tattoo ink supplier and type		Note
	Confirmed	Probable	Possible		Company	Ink	
New York	14	4	1	*M. chelonae*	A	Prediluted gray	Clinical and company A ink isolates indistinguishable
Washington	3	0	24	*M. abscessus*	B	Black	No NTM isolated from company B ink
Washington	2	0	2	*M. chelonae*	C	Gray	Clinical and company C ink isolates unrelated
Iowa	2	0	0	*M. chelonae*	C	Black	Available clinical isolates from Iowa cluster and Washington cluster 2 were indistinguishable
Colorado	1	0	0	*M. chelonae*	D	Black	Clinical isolate was unrelated to New York or Washington isolates, no NTM isolated from ink

cluster 2 was available for testing. A sample from an opened bottle of company C gray ink grew *M. chelonae*, which was unrelated to the Washington cluster 2 clinical isolate and was unrelated to New York isolates, based on PFGE patterns. Reviews of tattoo practices at the parlors associated with the clusters did not reveal other potential sources of contamination.

The Iowa Department of Public Health reported two confirmed *M. chelonae* cases. Patients were tattooed with black ink from company C. PFGE testing showed that two clinical isolates from Iowa and the clinical isolate from Washington cluster 2 were indistinguishable from each other, but unrelated to New York isolates. Ink and environmental samples were not available for testing.

The Colorado Department of Public Health and Environment reported one confirmed case of *M. chelonae* infection. PFGE testing showed that this strain was unrelated to any of the clinical and ink isolates identified in other clusters. Artists at the Colorado tattoo parlor reported using distilled or reverse osmosis water to dilute company D black ink. Although used for tattooing, the ink was labeled as a drawing ink, and specified as not indicated for tattooing. The artist rinsed needles with distilled or reverse osmosis water when switching colors of ink on the same client. An unopened bottle of company D black drawing ink, reverse osmosis water samples, and environmental samples were tested, but NTM were not recovered.

In March and April 2012, FDA conducted inspections of company A and company B ink manufacturing sites. Ingredients used in the manufacture of tattoo inks at those sites included a wide range of pigments, carrier solutions, and diluents, including distilled water in some formulations. Samples of unopened ink bottles, ink ingredients, environmental samples, distilled water, and tap water were tested at CDC and did not yield NTM.

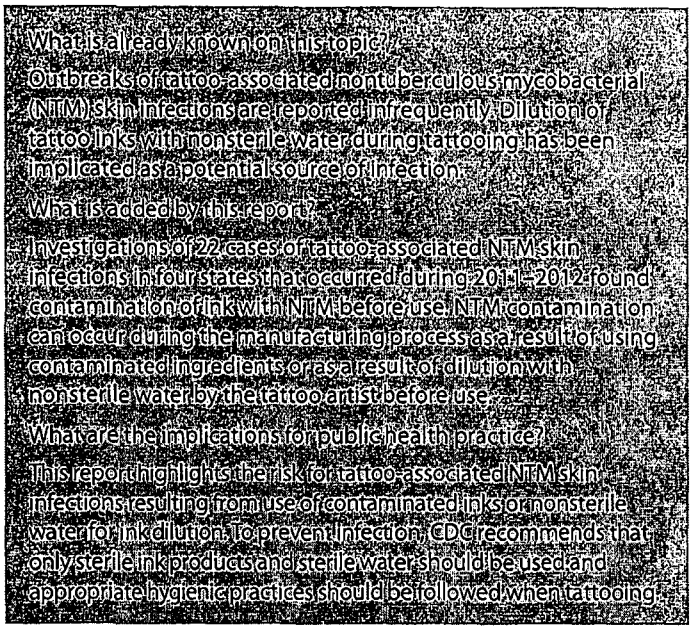
Reported by

Brenden Bedard, MPH, Byron Kennedy, MD, Monroe County Dept of Public Health; Vincent Escuyer, PhD, Kara Mitchell, PhD, Wadsworth Center, Mycobacteriology Laboratory, New York State Dept of Health. Jeffrey S. Duchin, MD, Public Health – Seattle & King County, Washington; Paul Pottinger, MD, Stanley Hurst, MD, Univ of Washington. Ken Sharp, MPA, Timothy Wickham, MPH, Iowa Dept of Public Health. Sarah Jackson, MPH, Wendy Bamberg, MD, Colorado Dept of Public Health and Environment. Pamela LeBlanc, MPH, Coordinated Outbreak Response and Evaluation Network; Linda M. Katz, MD, Office of Colors and Cosmetics, Center for Food Safety and Applied Nutrition, Food and Drug Administration. Taranisia MacCannell, PhD, Judith Noble-Wang, PhD, Heather O'Connell, PhD, Alexander Kallen, MD, Bette Jensen, MMSc, Div of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases; Duc B. Nguyen, MD, Michael H. Kinzer, MD, EIS officers, CDC. ***Corresponding contributors:*** *Duc B. Nguyen, vif8@cdc.gov, 404-639-0027; Michael H. Kinzer, michael.kinzer@kingcounty.gov, 206-263-8169.*

Editorial Note

This report describes cases of tattoo-associated NTM skin infections in four states. The use of ink contaminated before distribution or just before tattooing likely led to infections in each of the reported clusters. In the New York cluster, NTM isolates from clinical specimens, and unopened containers of company A prediluted gray ink were indistinguishable. In Washington cluster 2 and the Iowa cluster, intrinsic contamination of company C gray ink was indicated by indistinguishable *M. chelonae* clinical isolates from infected tattoo lesions, with no other common exposure except the brand of ink used for tattooing. NTM isolates matching cases were not cultured from any other brand of ink; however, whether the ink samples tested were from the same batches of inks used in the cases could not be determined.

The frequency of NTM skin and soft tissue infections occurring subsequent to tattooing is not known, but these events have been reported previously, and dilution of inks with nonsterile water during tattooing was implicated (*3–6*). Tattoo-associated NTM infections can range from mild inflammation (e.g., rash, papules, or nodules) to severe abscesses requiring



extensive and multiple surgical debridements. NTM infections are difficult to treat and can require a minimum of 4 months of treatment with a combination of two or more antibiotics. Physicians who encounter persistent papular rashes or nodules localized to newly tattooed areas should consider the possibility of an NTM infection.

Contamination of tattoo inks can occur during the manufacturing process and might persist if steps are not taken to eliminate harmful microbial contaminants in the finished product. A cross-sectional laboratory survey in 2010 of 58 unopened ink bottles from different manufacturers identified intrinsic contamination with a variety of organisms in 10% of these inks (*7*), but did not test for the presence of NTMs.

Many NTM species (e.g., *M. abscessus* and *M. chelonae*) are found in water, so the addition of nonsterile water to ink during its manufacture or at its point of use could lead to contamination with NTM (*3–5*), and potentially result in infections. In addition, a common misconception is that distilled and reverse osmosis water are sterile (*8*), leading to the mistaken assumption that these products are acceptable for diluting tattoo inks. Dilution of inks with nonsterile water or other ingredients at the point of use might lead to product contamination. Dilution of ink also will dilute preservatives, if present, and make them less effective.

Under the Federal Food, Drug, and Cosmetic Act, tattoo inks are considered to be cosmetics, and the pigments used in the inks are color additives requiring premarket approval (*9*). No specific FDA regulatory requirement explicitly provides that tattoo inks must be sterile. However, intradermal introduction of nonsterile substances, such as tattoo ink, can pose a health risk and is a public health concern.

The practice of tattooing may be regulated by local jurisdictions (*9*). Such regulations generally have required blood-borne pathogens training and the use of hygienic practice during tattooing. A few local jurisdictions, such as Los Angeles County (*10*), have issued requirements that sterile water be used in tattoo ink dilution.

The findings in this report are subject to at least the following limitation. Because on-site investigations took place months after cases were reported, potentially contaminated batches and ingredients, such as distilled water and pigments, were not available for testing. Similarly, water sources used for the manufacture of inks or for ink dilution when patients were tattooed were not available.

Because tattoo inks are injected intradermally, CDC recommends that ink manufacturers be held to higher product safety standards, which should include production of sterile inks. In addition, tattoo artists should 1) avoid using products not intended for use in tattooing; 2) avoid ink dilution before tattooing, and if dilution is needed, use only sterile water; 3) avoid use of nonsterile water to rinse equipment (e.g., needles) during tattoo placement; and 4) follow aseptic techniques during tattooing (e.g., hand hygiene and use of disposable gloves). To reduce their risk for infection, consumers should 1) use tattoo parlors registered by local jurisdictions; 2) request inks that are manufactured specifically for tattoos; 3) ensure that tattoo artists follow appropriate hygienic practices; 4) be aware of the potential for infection following tattooing, and seek medical advice if persistent skin problems occur; and 5) notify the tattoo artist and FDA's MedWatch program* if they experience an adverse event.

*Additional information available at http://www.fda.gov/safety/medwatch/howtoreport/default.htm.

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Court of Appeals No. 73225-1-I
(Snohomish County Cause #13-2-06924-3)

COURT OF APPEALS, DIVISION I
STATE OF WASHINGTON

ANNA CHESTER,

Appellant-Petitioner,

vs.

DEEP ROOTS ALDERWOOD, LLC, a Washington company; and BONNIE GILLSON,

Respondents.

DECLARATION OF MAILING

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Co-Attorneys for Petitioner

Shari M. Canet, does hereby declare the same under oath and penalty of perjury of the laws of the State of Washington:

On May 4, 2016, I served the Petition for Review in this matter based on the listing of attorneys in the April 4, 2016 letter from the Court of Appeals, Division I to appellate counsel transmitting the opinion. Ahrend Law Firm PLLC was not counsel of record in the Division I proceeding until January 19, 2016, and has not appeared in the trial court proceeding. Ahrend Law Firm PLLC had not received prior notice or service of the withdrawals or substitutions of counsel or parties.

On May 5, 2016, I re-served the Petition for Review in this matter by First Class Mail, postage prepaid, as follows:

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Signed at Moses Lake, Washington on May 5, 2016.

Shari M Canet

Shari M. Canet, Paralegal

CERTIFICATE OF SERVICE

The undersigned does hereby declare the same under oath and penalty of perjury of the laws of the State of Washington:

On May 5, 2016, I served the document to which this is annexed by First Class Mail, postage prepaid, as follows:

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and upon Petitioner's co-counsel, James S. Sorrels, via email pursuant to prior agreement for electronic service, at:

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Signed at Moses Lake, Washington on May 5, 2016.

Shari M. Canet, Paralegal