



PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

In accordance with [RCW 34.05.330](#), the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at <http://apps.leg.wa.gov/wac/default.aspx?cite=82-05>.

CONTACT INFORMATION *(please type or print)*

Petitioner's Name Gerald Steel
Name of Organization Representing "King County Citizens Against Fluoridation" and "Washington Action for Safe Water"
Mailing Address 7303 Young Rd. NW
City Olympia State WA Zip Code 98502
Telephone 360-867-1166 Email geraldsteel@yahoo.com

COMPLETING AND SENDING PETITION FORM

- Check all of the boxes that apply.
- Provide relevant examples.
- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: <http://www.leg.wa.gov/CodeReviser/Documents/RClst.htm>.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: State Board of Health

1. NEW RULE - I am requesting the agency to adopt a new rule.

The subject (or purpose) of this rule is: Set additional safety limits on fluoridation products in Washington State

The rule is needed because: Many fluoridation chemical additives have unsafe amounts of lead and arsenic

The new rule would affect the following people or groups: Potential to affect suppliers of fluoridation additives and will affect the public by making fluoridated water safer

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**BEFORE THE WASHINGTON STATE
BOARD OF HEALTH**

King County Citizens Against
Fluoridation, and Washington Action for
Safe Water,

Petitioners.

NO.

PETITION FOR NEW STATE
ADMINISTRATIVE RULE

COMES NOW the Petitioners, King County Citizens Against Fluoridation and
Washington Action for Safe Water (collectively "Citizens") with this Petition for adoption
of a new State Administrative Rule pursuant to RCW 34.05.330 and WAC 82-05-020.

PETITIONERS' CONTACT INFORMATION

First Petitioner's Name: King County Citizens Against Fluoridation ("KCCAF")

Mailing Address: c/o Audrey Adams
10939 SE 183rd Court
Renton, WA 98055

Second Petitioner's Name: Washington Action for Safe Water ("WASW")

PETITION FOR NEW STATE
ADMINISTRATIVE RULE - 1

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1 Mailing Address: c/o Scott Shock
2 337 24th Ave. E
3 Seattle, WA 98112

4 Petitioners' Representative: Gerald Steel
5 Attorney at Law
6 7303 Young Rd. NW
7 Olympia WA 98502
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8 AGENCY RESPONSIBLE FOR ADOPTING OR AMENDING RULES

9 Agency: State Board of Health ("Board")

10 SUMMARY OF ISSUE

11 Request that the Board adopt a new rule to only permit those fluoridation chemical
12 additives to be added to Group A public drinking water that do not add any lead or arsenic
13 to the drinking water

14 PROPOSED RULE

15 **Issue a regulation in substantially the following form:**

16 (1) Fluoridation chemical additives allowed to be added to Group A
17 public drinking water shall have test results that show the additive at full
18 strength contains no detectable lead or arsenic.

19 JUSTIFICATION

20 **Because the Maximum Contaminant Level Goal (safe level) for lead and arsenic is zero,**
21 **fluoridation chemicals used in Washington State should not be allowed to add**
22 **detectable lead or arsenic to Group A public drinking water.**

23 The Safe Drinking Water Act ("SDWA" - 42 USC 300f et seq.) directs the EPA to
24 regulate contaminants in public drinking water. 42 USC 300g-1(b)(4) sets the Goal and
25 Standards for clean-up of existing contaminants in public drinking water:

26
27 PETITION FOR NEW STATE
28 ADMINISTRATIVE RULE - 2

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1 (4) GOALS AND STANDARDS.-

2 (A) MAXIMUM CONTAMINANT LEVEL GOALS.-Each
3 maximum contaminant level goal established under this subsection shall be
4 set at the level at which no known or anticipated adverse effects on the health
5 of persons occur and which allows an adequate margin of safety.

6 (B) MAXIMUM CONTAMINANT LEVELS.-Except as provided
7 in paragraphs (5) and (6), each national primary drinking water regulation for
8 a contaminant for which a maximum contaminant level goal is established
9 under this subsection shall specify a maximum contaminant level for such
10 contaminant which is as close to the maximum contaminant level goal as is
11 feasible.

12 The Maximum Contaminant Level Goal ("MCLG") is set by the EPA as the highest safe
13 level in public drinking water for each regulated contaminant. Because it costs money to
14 remove contaminants in drinking water, the SDWA requires contaminants to be removed
15 only to economically feasible levels that are "as close to the maximum contaminant level goal
16 as is feasible." These economically feasible levels are called maximum contaminant levels.

17 But this concept in the SDWA does not consider purposefully adding contaminants
18 to drinking water especially when the contaminants are not being added to make water safe
19 and reliable. Fluoridation chemicals are added to public drinking water to distribute to
20 consumers substances that are intended to aid in the prevention of tooth decay disease and
21 not to make water safe and reliable. Petitioners submitted a separate petition to the Pharmacy
22 Quality Assurance Board to request that it take jurisdiction over fluoridation products when
23 the intent is to prevent tooth decay disease. A copy of the first part of that Petition is attached
24 hereto as Appendix B for informational purposes.

25 The authority of this Board under review is its authority to adopt rules for group A
26 public water systems necessary to assure safe and reliable public drinking water. (RCW
27 43.20.050(2)(a) - Attachment A1 hereto.) This Board should accept the premise that
28

1 chemicals unrelated to making water safe and reliable should not be allowed to be added to
2 group A public water systems when they take a contaminant level in the water above or
3 further above the safe level of that contaminant as established by EPA as the maximum
4 contaminant level goal.

5
6 Attachment A2 hereto is from 40 CFR 141.51, the implementing regulations of the
7 SDWA. It establishes that the maximum contaminant level goal (safe level) for lead and
8 arsenic in public drinking water is zero. This means that any addition of lead or arsenic to
9 group A public drinking water makes that water less safe. The mandate to this Board from
10 the legislature is to adopt rules for group A public water systems necessary to assure safe and
11 reliable public drinking water. (Attachment A1 hereto.) To implement this mandate, this
12 Board should adopt the proposed rule and not allow fluoridation chemicals to be added to
13 group A public water systems if the fluoridation chemicals at full strength have detectable
14 amounts of lead or arsenic. Allowing such products to be added to such water systems
15 would make the public drinking water less safe. It is contrary to this Board's legislative
16 mandate.

17
18 Attachments A3 to A10 hereto together are the NSF Fact Sheet on Fluoridation
19 Chemicals. It states that arsenic was detected in 43% of product samples. (Attachment A5
20 hereto). It also states that lead was detected in 2% of product samples. (Attachment A8
21 hereto.) But all samples were tested after dilution of the actual product. (Attachment A3
22 hereto.) Petitioners propose that testing be required for Washington with the chemicals at full
23 strength. The MCLG for lead and arsenic is zero and so no detectable lead and arsenic should
24

1 be added to public drinking water when the additive is not required to make the water safe
2 and reliable.

3 Thank you for consideration of this Petition.

4 **AUTHORITY OF THIS BOARD TO ADOPT AND AMEND RULES**

5
6 In general, administrative agencies such as this Board, have powers expressly granted
7 or necessarily implied from their statutory delegation of authority. *Tuerk v. State Department*
8 *of Licensing*, 123 Wn.2d 120, 124-25, 864 P.2d 1382 (1994). Such powers cannot amend or
9 conflict with a statute. (*Id.* at 125; *Association of Washington Business v. State Department*
10 *of Revenue*, 155 Wn.2d 430, 438-39. 120 P.3d 46 (2005).) The State Board of Health is
11 authorized to adopt rules by RCW 43.20.050(2) which states, in pertinent part, as follows:

12
13 (2) In order to protect public health, the state board of health shall:

14 (a) Adopt rules for group A public water systems, as defined in RCW
15 70.119A.020, necessary to assure safe and reliable public drinking water

16 **RESPONSES TO ITEMS IN WAC 82-05-020(1)(c)**

17 **(i) The rule is authorized**

18 The proposed rule is authorized by RCW 43.20.050(2)(a) and 34.05.330.

19 **(ii) The rule is needed**

20 The proposed rule is needed to avoid adding lead and arsenic to group A public drinking
21 water when any addition compromises the safety of that drinking water.

22 **(iii) The rule does not conflict with or duplicates other federal, state, or local laws**

1 The additive would still have to comply with ANSI/NSF Standard 60 as required by State
2 Board of Health WAC 246-290-220 but with the adoption of the proposed rule, fluoridation
3 chemicals would have an additional requirement.

4 **(iv) Alternatives to the rule do not exist that will serve the same purpose at less cost**

5 Without this rule, safety of group A public drinking water is being compromised.

6 **(v) The rule does not apply differently to public and private entities**

7 The proposed rule does not apply differently to public and private entities.

8 **(vi) The proposed rule serves the purposes for which it is being adopted**

9 The proposed rule serves the purpose for which it is being proposed for adoption.

10 **(vii) The rule imposes no unreasonable costs**

11 Fluoridation chemicals are optional in public water systems so this rule can always be
12 implemented by not using such chemicals which will lead to a cost savings. Tooth decay
13 reduction can be achieved by other more cost-effective methods. It is not the State Board of
14 Health jurisdiction to set optimum fluoridation levels unrelated to making water safe and
15 reliable. (See Appendix B hereto.)

16 **(viii) The proposed rule is clearly and simply stated**

17 The proposed rule is clearly and simply stated.

18 ###

19 ###

1 (ix) The rule is consistent with federal all law which applies to the same activity or
2 subject matter

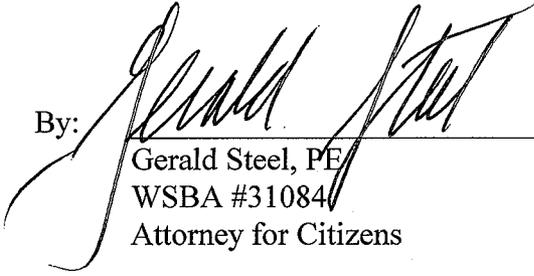
3 No federal law addresses the allowed lead and arsenic in fluoridation chemicals.

4 Attachments A1 to A10 and Appendix B are hereby incorporated into this Petition.

5 Dated this 2nd day of October, 2015.

6 Respectfully submitted,

7
8
9 By:



Gerald Steel, PE
WSBA #31084
Attorney for Citizens

RCW 43.20.050

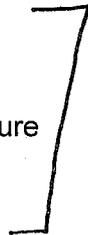
Powers and duties of state board of health — Rule making — Delegation of authority — Enforcement of rules.

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

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

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

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



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

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

(iii) Public water system management and reporting requirements;

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

(v) Public water system operation and maintenance requirements;

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

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

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

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

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

AI

40 CFR 141.51

§141.51 Maximum contaminant level goals for inorganic contaminants.

(a) [Reserved]

(b) MCLGs for the following contaminants are as indicated:

Contaminant	MCLG (mg/l)
Antimony	0.006
Arsenic	zero ¹
Asbestos	7 Million fibers/liter (longer than 10 µm)
Barium	2
Beryllium	.004
Cadmium	0.005
Chromium	0.1
Copper	1.3
Cyanide (as free Cyanide)	.2
Fluoride	4.0
Lead	zero
Mercury	0.002
Nitrate	10 (as Nitrogen)
Nitrite	1 (as Nitrogen)
Total Nitrate+Nitrite	10 (as Nitrogen)
Selenium	0.05
Thallium	.0005

¹This value for arsenic is effective January 23, 2006. Until then, there is no MCLG.

A2



NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

1. Fluorosilicic Acid: 6 mg/L.
2. Sodium Fluorosilicate: 2 mg/L.
3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

A4

Potential Contaminants

The NSF toxicology review for a chemical product considers all chemical ingredients in the product as well as the manufacturing process, processing aids, and other factors that have an impact on the contaminants present in the finished drinking water. This formulation review identifies all the contaminants that need to be analyzed in testing the product. For example, fluosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. The manufacturing process is documented by an NSF inspector at an initial audit of the manufacturing site and during each annual unannounced inspection of the facility. The manufacturing process, ingredients, and potential contaminants are reviewed annually by NSF toxicologists, and the product is tested for any potential contaminants. A minimum test battery for all fluoridation products includes metals of toxicological concern and radionuclides.

Many drinking water treatment additives, including fluoridation products, are transported in bulk via tanker trucks to terminals where they are transferred to rail cars, shipped to distant locations or transferred into tanker trucks, and then delivered to the water treatment plants. These tanker trucks, transfer terminals and rail cars are potential sources of contamination. Therefore, NSF also inspects, samples, tests, and certifies products at rail transfer and storage depots. It is always important to verify that the location of the product distributor (the company that delivers the product to the water utility) matches that in the official NSF Listing for the product (available at www.nsf.org).

NSF has compiled data on the level of contaminants found in all fluoridation products that have applied for, or have been listed by, NSF. The statistical results in Table 1 (attached) include the test results for these products, as well as the annual monitoring tests from the period 2000 to 2006. This includes 245 separate samples analyzed during this time period. The concentrations reported represent contaminant levels that would be expected when the product is dosed into water at the Maximum Use Level (MUL). Lower product doses would produce proportionately lower contaminant concentrations (e.g. a 0.6 mg/L fluoride dose would produce one half the contaminant concentrations listed in Table 1.)

Table 1 documents that there is no contamination of drinking water from the fluoridation products NSF has tested and certified. NSF issued previous summaries of contaminant levels in fluoridation products for earlier reporting periods in 1999 and 2003. While some contaminant levels in those earlier periods were slightly higher than the current data for certain contaminants, there has not been a single fluoride product tested since the initiation of the program in 1988 with a contaminant concentration in excess of its corresponding SPAC. The documented reduction of impurities for this most current time period is due, at least in part, to the effectiveness of NSF/ANSI Standard 60 and the NSF certification program for drinking water treatment additives, and demonstrates the effectiveness of the program. The reduction in impurities is further attested to by an article in the Journal of the American Water Works Association entitled, "Trace Contaminants in Water Treatment Chemicals."¹

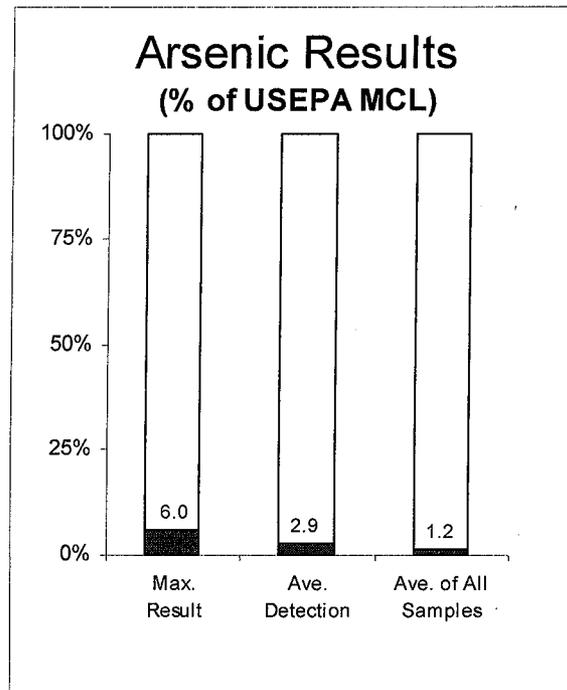
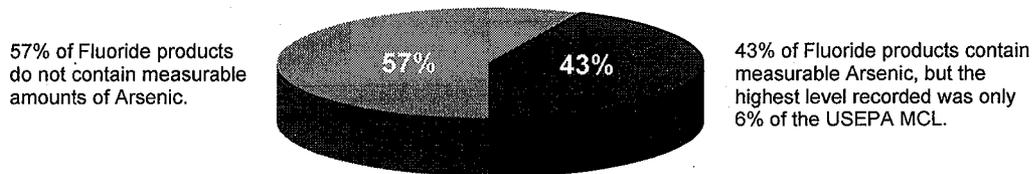
Arsenic

The results in Table 1 indicate that the most common contaminant detected in these products is arsenic, but it is detected in only 43% of the product samples. This means that levels of arsenic

¹ Brown, R., et al., "Trace Contaminants in Water Treatment Chemicals: Sources and Fate." Journal of the American Water Works Association 2004: 96:12:111.

in 57% of the samples were non-detectable, even though products are tested at 10 times their maximum use level. All detections were at levels below the Single Product Allowable Concentration, if the product is added to drinking water at (or below) its maximum use level. The SPAC, as defined in NSF/ANSI Standard 60, is one tenth of the US EPA's MCL. The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb (shown on Table 1), and the average concentration was 0.12 ppb. Even the highest concentration of 0.6 ppb was only detected because the standard requires testing the chemical at 10 times its maximum use level to detect these trace levels of contaminants. Had the dose of fluoridation additives been tested in water at the maximum use level, instead of at 10 times their maximum use levels, the arsenic concentration measured would have been below the 1 ppb reporting limit for arsenic for 100 percent of the samples measured.

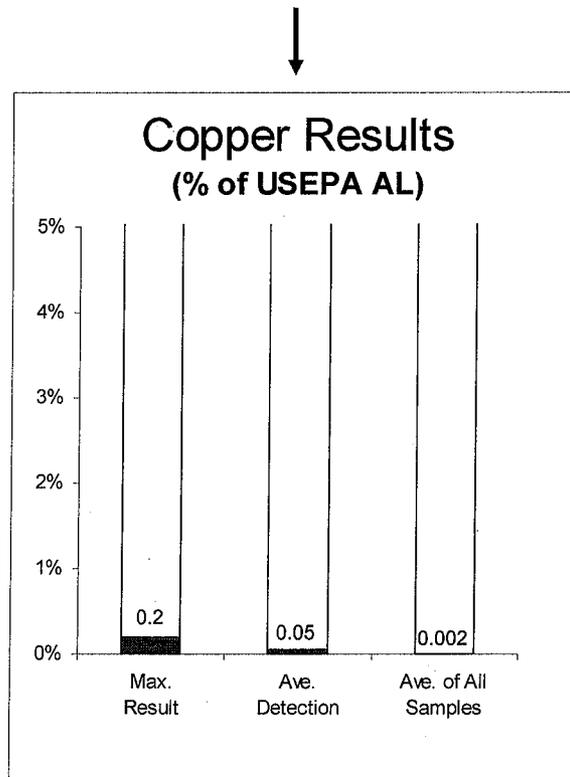
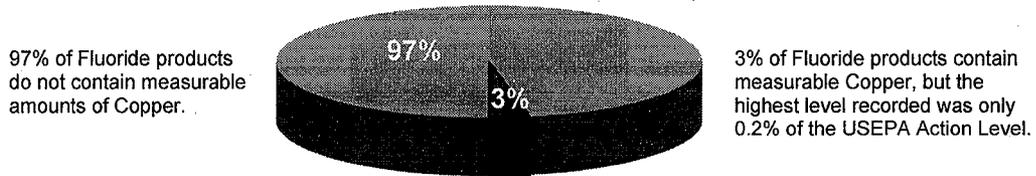
Figure A



Copper

The second most common contaminant found, and on a much less frequent basis, is copper, and 97% of all samples tested had no detectable levels of copper. The average concentration of copper has been 0.02 ppb with 2.6 ppb being the highest concentration detected. This is well below the 130 ppb SPAC requirement of NSF 60.

Figure B

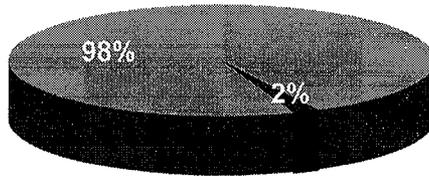


Lead

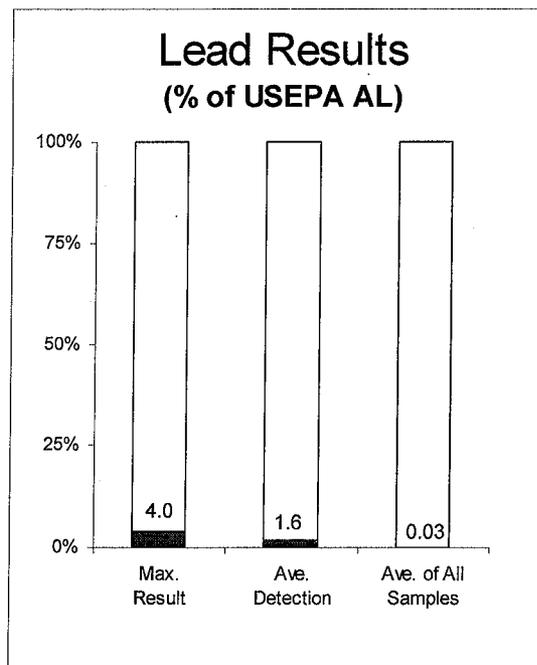
The third most common contaminant found is lead. It occurs on a much less frequent basis, and 98% of all samples tested had no detectable levels of lead. The average concentration of lead has been 0.005 ppb with 0.6 ppb being the highest concentration detected. This is well below the 1.5 ppb SPAC requirement of NSF 60.

Figure C

98% of Fluoride products do not contain measurable amounts of Lead.



2% of Fluoride products contain measurable Lead, but the highest level recorded was only 4% of the USEPA Action Level of 15ppb.



Radionuclides

Fluoridation products are also tested for radionuclides. All samples tested have not had any detectable levels of alpha or beta radiation.

Summary

In summary, the majority of fluoridation products as a class, based on NSF test results, do not add measurable amounts of arsenic, lead, other heavy metals, or radionuclide contamination to drinking water.

Additional information on fluoridation of drinking water can be found on the following web sites:

American Water Works Association (AWWA) Fluoridation Chemical Standards

<http://www.awwa.org/Bookstore/producttopicsresults.cfm?MetaDataID=121&navItemNumber=5093>

American Water Works Association (AWWA) position

<http://www.awwa.org/Advocacy/pressroom/fluoride.cfm>

American Dental Association (ADA) <http://www.ada.org/public/topics/fluoride/index.asp>

U.S. Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov/fluoridation>

Table 1

	Percentage of Samples with Detectable Levels	Mean Contaminant Concentration in all samples (ppb)	Mean Contaminant Concentration in detectable samples (ppb)	Maximum Contaminant Concentration in detectable samples (ppb)	NSF/ANSI Standard 60 Single Product Allowable Concentration	US EPA Maximum Contaminant or Action Level
Antimony	0%	ND	ND	ND	0.6	6
Arsenic	43%	0.12	0.29	0.6	1	10
Barium	<1%	0.001	0.3	0.3	200	2000
Beryllium	0%	ND	ND	ND	0.4	4
Cadmium	1%	0.001	0.08	0.12	0.5	5
Chromium	<1%	0.001	0.15	0.2	10	100
Copper	3%	0.02	0.68	2.6	130	1300
Lead	2%	0.005	0.24	0.6	1.5	15
Mercury	<1%	0.0002	0.04	0.04	0.2	2
Radionuclides – alpha pCi/L	0%	ND	ND	ND	1.5	15
Radionuclides – beta mrem/yr	0%	ND	ND	ND	0.4	4
Selenium	<1%	0.016	1.95	3.2	5	50
Thallium	<1%	0.0003	0.04	0.06	0.2	2

Abbreviations used in this Fact Sheet

ANSI – American National Standards Institute

AWWA – American Water Works Association

AWWARF – American Water Works Association Research Foundation

ASDWA – Association of State Drinking Water Administrators

COSHEM – Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MCL – maximum contaminant level

mrem/yr – millirems per year – measurement of radiation exposure dose

MUL – Maximum use level

NSF – NSF International (formerly the National Sanitation Foundation)

ppb – parts per billion

PCi/L – pico curies per liter – concentration of radioactivity

SPAC – Single Product Allowable Concentration

Appendix B



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Name of Organization Representing "King County Citizens Against Fluoridation" and "Washington Action for Safe Water"
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- Include suggested language for a rule, if possible.
- Attach additional pages, if needed.
- Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: <http://www.leg.wa.gov/CodeReviser/Documents/RClst.htm>.

INFORMATION ON RULE PETITION

Agency responsible for adopting or administering the rule: Pharmacy Quality Assurance Commission

1. NEW RULE - I am requesting the agency to adopt a new rule.

The subject (or purpose) of this rule is: Clarify Commission jurisdiction over fluoridation products

The rule is needed because: The Commission and Public are not clear about such Commission jurisdiction

The new rule would affect the following people or groups: Potential to affect suppliers of fluoridation products

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**BEFORE THE WASHINGTON STATE
PHARMACY QUALITY ASSURANCE COMMISSION**

King County Citizens Against
Fluoridation, and Washington Action for
Safe Water,

Petitioners.

NO.

PETITION FOR NEW STATE
ADMINISTRATIVE RULE

COMES NOW the Petitioners, King County Citizens Against Fluoridation and
Washington Action for Safe Water (collectively "Citizens") with this Petition for adoption
of a new State Administrative Rule pursuant to RCW 34.05.330 and WAC 82-05-020.

PETITIONERS' CONTACT INFORMATION

First Petitioner's Name: King County Citizens Against Fluoridation ("KCCAF")

Mailing Address: c/o Audrey Adams
10939 SE 183rd Court
Renton, WA 98055

Second Petitioner's Name: Washington Action for Safe Water ("WASW")

1 Mailing Address: c/o Scott Shock
2 337 24th Ave. E
3 Seattle, WA 98112

4 Petitioners' Representative: Gerald Steel
5 Attorney at Law
6 7303 Young Rd. NW
7 Olympia WA 98502
8 Tel/Fax (360) 867-1166
9 geraldsteel@yahoo.com

8 AGENCY RESPONSIBLE FOR ADOPTING OR AMENDING RULES

9 Agency: Pharmacy Quality Assurance Commission ("Commission")

10 SUMMARY OF ISSUE

11 Request that the Commission adopt a new rule to clarify that fluoridation chemical
12 additives (whether or not certified under NSF/ANSI Standard 60) and fluoridated drinking
13 waters (bottled and/or from public water systems, that are fluoridated with such additives)
14 are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the intended
15 use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries
16 disease (tooth decay, cavities).
17

18 PROPOSED RULE

19 Issue a regulation in substantially the following form:

20 (1) Fluoridation chemical additives (whether or not certified under
21 NSF/ANSI Standard 60) and fluoridated drinking waters (bottled and/or from
22 public water systems, that are fluoridated with such additives) are drugs
23 pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the
intended use is to aid in the prevention, mitigation, and/or prophylactic
treatment of dental caries disease (tooth decay, cavities).

24 (2) Fluoridation chemical additives include:
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- 1 (a) Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic
2 Acid).
3 (b) Sodium Fluorosilicate (aka Sodium Silicofluoride).
4 (c) Sodium Fluoride.
5 (d) Calcium Fluoride.

6 (3) It is presumed that the intended use of such additives and such
7 fluoridated drinking waters is to aid in the prevention, mitigation, and/or
8 prophylactic treatment of dental caries disease (tooth decay, cavities).

9 (d) The pharmacy quality assurance commission has jurisdiction to
10 ensure that distribution, wholesaling, and manufacturing of fluoridation
11 chemical additive drugs and fluoridated water drugs in this state provide for
12 the protection and promotion of the public health, safety, and welfare.

13 JUSTIFICATION

14 **All of the statutes in this state that define drugs makes substances drugs if the intended
15 use is the “mitigation, treatment, or prevention of disease in human beings.” No statute
16 exempts fluoridation chemical additives or fluoridated waters made from these
17 additives from these drug statutes.**

18 The term “drugs” is defined in RCW 18.64.011(12)(b) to include “Substances
19 intended for use in the . . . mitigation, treatment, or prevention of disease in human beings.”
20 (Attachment A1 hereto.) The other state statutory definitions of drugs (RCW 69.04.009(2)
21 and 69.41.010(9)(b)) are the same or similar. (Attachments A2 and A3 hereto.)

22 The powers and duties of the commission include:

23 Promulgate rules for the . . . distribution, wholesaling, and manufacturing of
24 drugs . . . for the protection and promotion of the public health, safety, and
25 welfare.

26 (RCW 18.64.005(7) - Attachment A4 hereto.) The word “distribute” means the delivery of
27 a drug . . . other than by administering or dispensing.” (RCW 18.64.011(10) - Attachment
28 A1 hereto.) The commission shall also “Assist the regularly constituted enforcement
agencies of this state in enforcing all laws pertaining to drugs.” (RCW 18.64.005(6) -

1 Attachment A4 hereto.) Clearly, the commission has jurisdiction to regulate distribution,
2 wholesaling, and manufacturing of drugs and to participate in enforcement of all drug laws.

3 The proposed regulation simply states that when the intended use is to aid in the
4 prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay,
5 cavities), that fluoridation chemical additives and fluoridated drinking waters are drugs
6 within the regulatory jurisdiction of the commission.
7

8 The proposed regulation creates a presumption that the intended use of fluoridation
9 chemical additives and fluoridated drinking water is to aid in the prevention, mitigation,
10 and/or prophylactic treatment of dental caries disease (tooth decay, cavities). This
11 presumption is justified for fluoridation chemical additives that comply with ANSI/NSF
12 Standard 60 because the NSF Fact Sheet on Fluoridation Chemicals states that these
13 fluorides are “added to water for the public health benefit of preventing and reducing tooth
14 decay.” (Attachment A5 hereto.) All fluoridation chemical additives used in Group A public
15 water systems in Washington State currently must be certified to comply with ANSI/NSF
16 Standard 60. (WAC 246-290-220(3) - Attachment A6 hereto.)
17

18 Because all fluoridation chemical additives are properly presumed to be added to
19 prevent tooth decay disease, public water with these chemicals added should also be
20 presumed to be intended to prevent tooth decay disease. The U.S. Public Health Service and
21 U.S. Department of Health and Human Services recently released its latest recommendation
22 for using fluoridated water “for the Prevention of Dental Caries.” (Attachment A7 hereto.)
23

24 There is only one state statute that directly addresses fluoridation. (RCW 57.08.012 -
25 Attachment A8 hereto.) This statute gives a water district the power to fluoridate its water
26

1 supply system. But this statute does not say that the implementation of fluoridation can
2 avoid any associated legal requirements. There may be zoning and building code
3 requirements that must be met. There are public water system design and monitoring
4 requirements that must be met. There are requirements that fluoridation chemical additives
5 meet ANSI/NSF Standard 60. (Attachment A6 hereto.) Because the fluoridation chemical
6 additives and fluoridated waters are drugs, the proposed regulation clarifies that there will
7 have to be compliance with state drug laws and regulations.
8

9 It has been stated that the Supreme Court decided in *Kaul v. City of Chehalis*, 45
10 Wn.2d 616, 277 P.2d 352 (1954) that the City of Chehalis was not selling drugs when it sold
11 fluoridated water. In that case, the *Kaul* Court states:
12

13 Appellant's remaining assignments of error are directed to the trial court's
14 conclusions: . . . that the city is not engaged in selling drugs . . .

15 We have considered these assignments of error. It would add nothing to
16 discuss them in detail. They are not well taken.

17 (*Kaul* at 625.) Attachments A-26 to A-69 hereto are all of the briefing reviewed by the *Kaul*
18 Court in reaching its decision. While the Brief of Appellant assigns error to the trial court
19 conclusion that the City was not selling drugs (Attachment A-37 hereto), the Brief of
20 Appellant fails to argue this assignment of error. (*See* Attachments A-26 to A-49 hereto.)
21 "If a party fails to support assignments of error with legal arguments, they will not be
22 considered on appeal." (*Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619,
23 624, 818 P.2d 1056 (1991).) So the proper interpretation of the *Kaul* Court's cryptic
24 statement quoted above, is that *Kaul* failed to support this assignment of error with legal
25 argument, so it was not considered on appeal and "not well taken" for this reason.
26

1 Subsequent cases quoting *Kaul* did not consider the original Kaul briefing and did not realize
2 that the *Kaul* Court's comment that the assignment of error regarding "selling drugs" was
3 "not well taken" was only because the assignment was not supported with legal argument in
4 the Brief of Appellant.

5
6 Some have stated that the addition of fluoride to public drinking water is regulated
7 by the Safe Drinking Water Act ("SDWA"). This is not accurate when the finished fluoride
8 levels are below 2 ppm (2 mg/Liter). Steven Neugeboren is the head of the Water Law
9 Office of U.S. EPA and is responsible for EPA interpretations of the SDWA.¹ In a letter
10 dated 2-24-13 (Attachments A9 and A10 hereto), he states that under the SDWA, "EPA does
11 not have responsibility for substances added to water solely for preventative health care
12 purposes, such as fluoride." (Attachment A9 hereto.) He states,

13
14 The Department of Health and Human Services (HHS) acting through the
15 FDA, remains responsible for regulating the addition of drugs to water
supplies for health care purposes.

16 (*Id.*)

17 The State Board of Health ("SBOH") has for many years had regulations WAC 246-
18 290-220(3) (Attachment A6 hereto) and WAC 246-290-460 (Attachment A11 hereto):

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

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

25 ¹ EPA is the federal agency responsible for interpreting the SDWA because the SDWA is
26 administered by EPA.

1 (WAC 246-290-460 - Attachment A11 hereto). However, to the degree that this regulation
2 seeks to set “optimal levels” of fluoride for health care purposes (currently set at “0.8 through
3 1.3 mg/L” but currently proposed to be amended to “0.7 mg/L”) the SBOH has exceeded its
4 authority under RCW 43.20.050(2) (Attachment A12 hereto) where its only relevant
5 authority is to assure “safe” public drinking water. SBOH authority does not reach to
6 manufacturing and distribution of drugs and establishing dosing levels in public water for
7 preventative health care purposes. When drugs are distributed to consumers in public water,
8 it is the commission who has authority over the drug aspects and the SBOH only has
9 jurisdiction over drinking water safety and reliability unrelated to preventative health care
10 purposes.
11

12 Some have stated that the SBOH fluoride regulations in WAC 246-290-220(3) and
13 246-290-460 (Attachments A6 and A11 hereto) are related to the requirements of the Safe
14 Drinking Water Act (“SDWA”). But the EPA, the agency who administers the SDWA,
15 states, “neither WAC 246-290-220(3) nor WAC 246-290-460 are related to the requirements
16 of the Federal Safe Drinking Water Act in Washington State.” (Attachment A13 hereto.)
17

18 Very recently, on September 23, 2015, the U.S. FDA ruled that bottled fluoridated
19 municipal water is a drug when a drug claim has been made. (Attachments A14 and A15
20 hereto.) Three Requests for Designation were made to the FDA for Libera Bottled
21 Fluoridated Water each using a different fluoridation chemical: Sodium Fluoride; Sodium
22 Fluorosilicate; and Fluorosilicic Acid. (Attachment A14 hereto.) All fluoridation chemicals
23 were to be ANSI/NSF Standard 60 certified and added to municipal water to provide 0.7
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1 mg/L Fluoride. The drug claim was “this drinking water is intended for use in the prevention
2 of tooth decay disease.” (*Id.*) The FDA states:

3 Therefore, your proposed product (if marketed with your proposed claim)
4 would be a drug as that term is defined in section 201(g)(1)(B) [codified at
5 21 USC 321(g)(1)(B)] of the Federal Food, Drug, and Cosmetic Act (the
6 Act).

7 (*Id.*)

8 The intended use of the proposed bottled fluoridated municipal drinking water is the
9 same as the intended use for fluoridated municipal drinking water distributed to consumers’
10 homes through a piping system. The fluoridated municipal drinking water is the same
11 “substance” whether it is distributed in bottles or pipes. As discussed earlier (*supra* at 3) the
12 definition of a drug in RCW 18.64.011(12)(b) (Attachment A1 hereto) and RCW
13 69.41.010(9)(b) (Attachment A3 hereto) includes:

14 (b) Substances intended for use in the . . . prevention of disease in human
15 beings.

16 This definition includes such substances no matter how they are distributed to the consumer.

17 This commission should adopt the proposed rule because when fluoridation chemical
18 additives and fluoridated drinking waters have the intended use to aid in the prevention,
19 mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities), they
20 are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) and the commission
21 has jurisdiction over manufacturing, wholesaling, and distribution of these drugs as well as
22 enforcement authority to ensure that there is compliance with state and federal drug laws.

23 Because the commission has not previously recognized its authority in these matters, and the
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1 public is not aware of this commission authority, it is advisable that this regulation be
2 adopted to avoid misunderstandings.

3 Thank you for consideration of this Petition.

4 **AUTHORITY OF THIS COMMISSION TO ADOPT AND AMEND RULES**

5 In general, administrative agencies such as this Commission, have powers expressly
6 granted or necessarily implied from their statutory delegation of authority. *Tuerk v. State*
7 *Department of Licensing*, 123 Wn.2d 120, 124-25, 864 P.2d 1382 (1994). Such powers
8 cannot amend or conflict with a statute. (*Id.* at 125; *Association of Washington Business v.*
9 *State Department of Revenue*, 155 Wn.2d 430, 438-39. 120 P.3d 46 (2005).) The Pharmacy
10 Quality Assurance Commission is authorized to adopt rules by RCW 18.64.005 which states,
11 in pertinent part, as follows:
12

13 The commission shall:

14
15 (7) Promulgate rules for the dispensing, distribution, wholesaling, and
16 manufacturing of drugs and devices and the practice of pharmacy for the
protection and promotion of the public health, safety, and welfare. . . .

17 This Commission also has authority under RCW 34.05.230 to adopt interpretative statements
18 and adopt interpretative rules. *Association of Washington Business v. State Department of*
19 *Revenue*, 155 Wn.2d 430, 438-45, 120 P.3d 46 (2005).

20 **RESPONSES TO ITEMS IN WAC 82-05-020(1)(c)**

21 **(i) The rule is authorized**

22 The proposed rule is authorized by RCW 18.64.005 and 34.05.230.

23 **(ii) The rule is needed**

24 The proposed rule is needed to interpret the commission jurisdiction with respect to
25
26

1 fluoridation chemical additives and fluoridated drinking water for the benefit of the
2 commission and the public.

3 **(iii) The rule does not conflict with or duplicates other federal, state, or local laws**

4 The proposed rule clarifies and interprets existing state law that gives jurisdiction to the
5 commission to regulate substances that include fluoridation chemical additives and
6 fluoridated drinking water when these substances meet the state definition of drugs.
7

8 **(iv) Alternatives to the rule do not exist that will serve the same purpose at less cost**

9 The purpose of the proposed rule is to clarify jurisdiction of the commission so that it can
10 provide protection and promotion of the public health, safety, and welfare by implementing
11 drug laws for substances that are drugs but that are not currently being regulated as drugs by
12 any state agency. No other state agency has authority to adopt and implement drug laws, so
13 no alternative exists.
14

15 **(v) The rule does not apply differently to public and private entities**

16 The proposed rule does not apply differently to public and private entities.

17 **(vi) The proposed rule serves the purposes for which it was adopted**

18 The proposed rule serves the purpose for which it is being proposed for adoption.
19

20 **(vii) The rule imposes no unreasonable costs**

21 There are no costs imposed on others by this rule in that the rule just clarifies jurisdiction of
22 the commission.

23 **(viii) The proposed rule is clearly and simply stated**

24 The proposed rule is clearly and simply stated.
25
26

1 **(ix) The rule is consistent with federal law which applies to the same activity or subject**
2 **matter**

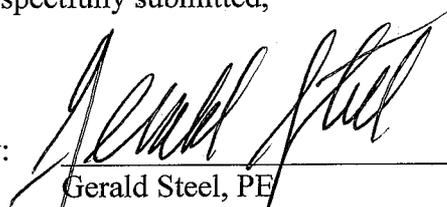
3 The proposed rule is consistent with federal laws defining drugs as demonstrated in
4 Attachment A14 hereto. (*Supra* at 7-8.)

5 Attachments A1 to A15 and A-26 to A-69 hereto are hereby incorporated into this
6 Petition.

7 Dated this 2nd day of October, 2015.

8 Respectfully submitted,

9
10
11 By:



Gerald Steel, PE
WSBA #31084
Attorney for Citizens

RCW 18.64.011**Definitions.**

*** CHANGE IN 2015 *** (SEE 5460-S.SL) ***

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

- (1) "Administer" means the direct application of a drug or device, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject.
- (2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a business license application and a business license expiration date common to each renewable license endorsement.
- (3) "Commission" means the pharmacy quality assurance commission.
- (4) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription.
- (5) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.
- (6) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.
- (7) "Department" means the department of health.
- (8) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.
- (9) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.
- (10) "Distribute" means the delivery of a drug or device other than by administering or dispensing.
- (11) "Drug" and "devices" do not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes. "Drug" also does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than human beings.
- (12) "Drugs" means:
 - (a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
 - (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;
 - (c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or
 - (d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.
- (13) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes a freestanding outpatient surgery center or a

A1

RCW 69.04.009**"Drugs."**

The term "drug" means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of human beings or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

[2009 c 549 § 1018; 1945 c 257 § 10; Rem. Supp. 1945 § 6163-59. Prior: 1907 c 211 § 2.]

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RCW 69.41.010**Definitions.**

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

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

(a) A practitioner; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Community-based care settings" include: Community residential programs for persons with developmental disabilities, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; and assisted living facilities licensed under chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

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

(4) "Department" means the department of health.

(5) "Dispense" means the interpretation of a prescription or order for a legend drug and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

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

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

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

(9) "Drug" means:

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

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

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

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

A3

RCW 18.64.005**Commission — Powers and duties.**

The commission shall:

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

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NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

AS

§ 246-290-220. Drinking water materials and additives.

Washington Administrative Code

**Title 246. Health, Department of
WATER SYSTEMS**

Chapter 246-290. Group A public water supplies

Part 3. DESIGN OF PUBLIC WATER SYSTEMS

Current through Register Vol. 15-18, September 15, 2015

§ 246-290-220. Drinking water materials and additives

- (1) All materials shall conform to the ANSI/NSF Standard 61 if in substantial contact with potable water supplies. For the purposes of this section, "substantial contact" means the elevated degree that a material in contact with water may release leachable contaminants into the water such that levels of these contaminants may be unacceptable with respect to either public health or aesthetic concerns. It should take into consideration the total material/water interface area of exposure, volume of water exposed, length of time water is in contact with the material, and level of public health risk. Examples of water system components that would be considered to be in "substantial contact" with drinking water are filter media, storage tank interiors or liners, distribution piping, membranes, exchange or adsorption media, or other similar components that would have high potential for contacting the water. Materials associated with components such as valves, pipe fittings, debris screens, gaskets, or similar appurtenances would not be considered to be in substantial contact.
- (2) Materials or additives in use prior to the effective date of these regulations that have not been listed under ANSI/NSF Standard 60 or 61 may be used for their current applications until the materials are scheduled for replacement, or that stocks of existing additives are depleted and scheduled for reorder.
- (3) Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60. The maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice.]
- (4) Any products used to coat, line, seal, patch water contact surfaces or that have substantial water contact within the collection, treatment, or distribution systems must comply with the appropriate ANSI/NSF Standard 60 or 61. Application of these products must comply with recommendations contained in the product certification.
- (5) The department may accept continued use of, and proposals involving, certain noncertified chemicals or materials on a case-by-case basis, if all of the following criteria are met:
 - (a) The chemical or material has an acknowledged and demonstrable history of use in the state for drinking water applications;

U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries

U.S. DEPARTMENT OF
HEALTH AND HUMAN
SERVICES FEDERAL PANEL
ON COMMUNITY WATER
FLUORIDATION

Through this final recommendation, the U.S. Public Health Service (PHS) updates and replaces its 1962 Drinking Water Standards related to community water fluoridation—the controlled addition of a fluoride compound to a community water supply to achieve a concentration optimal for dental caries prevention.¹ For these community water systems that add fluoride, PHS now recommends an optimal fluoride concentration of 0.7 milligrams/liter (mg/L). In this guidance, the optimal concentration of fluoride in drinking water is the concentration that provides the best balance of protection from dental caries while limiting the risk of dental fluorosis. The earlier PHS recommendation for fluoride concentrations was based on outdoor air temperature of geographic areas and ranged from 0.7–1.2 mg/L. This updated guidance is intended to apply to community water systems that currently fluoridate, or that will initiate fluoridation, and is based on considerations that include:

- Scientific evidence related to the effectiveness of water fluoridation in caries prevention and control across all age groups,
- Fluoride in drinking water as one of several available fluoride sources,
- Trends in the prevalence and severity of dental fluorosis, and
- Current evidence on fluid intake of children across various outdoor air temperatures.

BACKGROUND

Because fluoridation of public drinking water systems had been demonstrated as effective in reducing dental caries, PHS provided recommendations regarding optimal fluoride concentrations in drinking water for community water systems in 1962.^{2,3} The U.S. Department of Health and Human Services (HHS) is releasing this updated PHS recommendation because of new data that address changes in the prevalence of dental fluorosis, the relationship between water intake and outdoor temperature in children, and the contribution of fluoride in drinking water to total fluoride exposure in the United States. Although PHS recommends community water fluoridation as an effective public health intervention, the decision to fluoridate water systems is made by state and local governments.

Address correspondence to: Barbara F. Gooch, DMD, MPH, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Oral Health, 4770 Buford Hwy. NE, MS F-80, Atlanta, GA 30341-3717; tel. 770-488-6054; fax 770-488-6080; e-mail <bgooch@cdc.gov>.

RCW 57.08.012**Fluoridation of water authorized.**

A water district by a majority vote of its board of commissioners may fluoridate the water supply system of the water district. The commissioners may cause the proposition of fluoridation of the water supply to be submitted to the electors of the water district at any general election or special election to be called for the purpose of voting on the proposition. The proposition must be approved by a majority of the electors voting on the proposition to become effective.]

[1988 c 11 § 2.]

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
GENERAL COUNSEL

February 14, 2013

Gerald Steel, PE
7303 Young Road NW
Olympia, WA 98502

Dear Mr. Steel:

This is in response to your letter of December 28, 2012 to EPA Administrator Lisa Jackson in which you asked several questions about the status of an MOU between EPA and the Federal Drug Administration (FDA) published in 1979. I am replying on behalf of her.

Your first question is whether, from the viewpoint of EPA, the purpose of a 1979 Memorandum of Understanding (MOU) between EPA and the Federal Drug Administration (FDA) was "to take away from FDA, and give to EPA, responsibility for regulating public drinking water additives intended for preventative health care purposes and unrelated to contamination of public drinking water?" Your second question is whether, if that was the purpose of the 1979 MOU, the MOU was terminated through a subsequent Federal Register notice.

The answer to your first question is no, so there is no need to address your second question. The purpose of the MOU was not to shift any responsibilities between the Agencies. Rather, it was to help facilitate effective coordination of our respective legal authorities. Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than to limit the addition of such substances to protect public health or to prevent such substances from interfering with the effectiveness of any required treatment techniques. SDWA Section 1412(b)(11); see also A Legislative History of the Safe Drinking Water Act, Committee Print, 97th Cong, 2d Session (February 1982) at 547. The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.]]

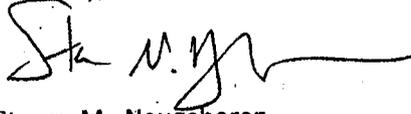
The 1979 MOU was intended to address contamination of drinking water supplies as a result of direct or indirect additives to drinking water, not to address the addition of substances solely for preventative health purposes. 44 Fed. Reg. 42775 (July 20, 1979) ("EPA and FDA agree: (1) that *contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem...*") (emphasis added). It was intended to avoid potentially duplicative regulation of "food", which FDA had, in the past, considered to include drinking water. 44 Fed. Reg. 42775 (July 20, 1979). The MOU did not address drugs or other substances added to water for health care purposes.

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Gerald Steel, PE
February 14, 2013
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I hope that this has adequately answered your inquiry. Please do not hesitate to contact Carrie Wehling of my staff (202-564-5492) if you have further questions about this.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven M. Neugeboren", with a long horizontal flourish extending to the right.

Steven M. Neugeboren
Associate General Counsel
Water Law Office

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WAC 246-290-460**Fluoridation of drinking water.**

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

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

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

(a) Daily monitoring.

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

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

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

(b) Monthly split sampling.

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

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

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

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

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

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

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

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

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

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RCW 43.20.050**Powers and duties of state board of health — Rule making — Delegation of authority — Enforcement of rules.**

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

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

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

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

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

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

(iii) Public water system management and reporting requirements;

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

(v) Public water system operation and maintenance requirements;

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

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

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

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

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 10

1200 Sixth Avenue, Suite 900
Seattle, WA 98101-3140

OCT 10 2012

OFFICE OF
WATER AND WATERSHEDS

Mr. Gerald Steel, PE
Attorney at Law
7303 Young Road NW
Olympia, Washington 98502

Dear Mr. Steel:

Your letter dated August 3, 2012, has been forwarded to the Office of Water and Watersheds for a response because my office is responsible for the implementation of the drinking water regulations. In your letter, you reiterate certain provisions of the Safe Drinking Water Act as we described them in letters from our office dated April 7, 2011, and November 17, 2011.

You go on to refer to various sections of the Washington Administrative Code, specifically WAC 246-290-220(3), which addresses treatment chemicals added to drinking water and WAC 246-290-460, which addresses drinking water fluoridation practices.

As noted in the U.S. Environmental Protection Agency (EPA) letter of November 17, 2011, neither WAC 246-290-220(3) nor WAC 246-290-460 are related to the requirements of the Federal Safe Drinking Water Act in Washington State.]

You ask if there is any law, regulation, or directive giving the EPA authority to prevent the Food and Drug Administration and/or Health and Human Services from exercising their drug authority to make a finding that fluoride products added to drinking water are drugs and if there is any law, regulation or directive giving the EPA authority to reverse any FDA regulatory action resulting from such a finding. The answer to both of these questions is no. The EPA has no authority to intervene in the actions of these agencies. If you have additional questions, please contact Fredianne Gray, our Regulatory Fluoride expert, at (206) 553-6387.

Sincerely

A handwritten signature in cursive script, appearing to read "Daniel D. Opalski".

Daniel D. Opalski
Office of Water and Watersheds

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Office of Combination Products
WO 32, Room 5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

September 23, 2015

Mr. Gerald Steel, PE
Attorney-At-Law
7303 Young Road, NW
Olympia, WA 98502

Re: "Submittal of Three Requests for Designation
for Libera Bottled Fluoridated Water each using a Different Fluoridation Chemical"
Dated: September 2, 2015
Received: September 2, 2015

Dear Mr. Steel:

For the reasons discussed below, we disagree that our previous legal reasoning is, as you indicate below, "no longer valid." As we have previously communicated to you, and as stated in the preamble to 21 CFR Part 3, Part 3 "does not apply to foods, veterinary products, or cosmetics" (56 FR 58754), and jurisdictional questions concerning a product that may be within the jurisdiction of the Center for Food Safety and Applied Nutrition (CFSAN) are outside the scope of 21 CFR part 3 and section 563 of the FD&C Act. In contrast to your characterization, the Center for Food Safety and Applied Nutrition's (CFSAN's) recent communication to you (Letter from F. Billingslea dated August 7, 2015, attached) does not state that your proposed bottled water product with the claim discussed below ("this drinking water is intended for use in the prevention of tooth decay disease") is "not a food under their [CFSAN's] jurisdiction." Instead, Ms. Billingslea stated that this proposed labeling statement "is not an authorized claim on food labeling under Section 403(r) of the Act." Ms. Billingslea further recommended that you contact Ms. Barbara Gould in FDA's Center for Drug Evaluation and Research (CDER) if you wished to market a bottled water product with this claim.

Ms. Billingslea recommended contacting CDER because you propose to market your product with a therapeutic claim. Your proposed claim would establish that your product is intended to prevent disease. Therefore, your proposed product (if marketed with your proposed claim) would be a drug as that term is defined in section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

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Mr. Gerald Steel, PE
Attorney-At-Law
September 23, 2015
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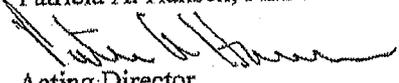
However, the fact that your proposed product (if marketed with your proposed claim) would be a drug under the Act does not mean that your product is not also a food. To the contrary, the definitions of "food" and "drug" under the Act are not mutually exclusive. *See, e.g., Nutrilab v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983). It is commonplace for FDA to take regulatory action with respect to food products that are promoted for conditions that cause the products to be drugs as well as foods.

Accordingly, we believe that our previous legal reasoning continues to apply, and your most recent requests fall outside the scope of the regulation and statutory provisions that authorize requests for designation. As a result, we are not treating your submissions regarding fluoridated bottled water as requests for designation. Instead, we are treating them as informal inquiries.

We hope it is helpful for you to know that your proposed product (if marketed with your proposed claim) would be both a food and a drug under the Act. We note that if you were to remove your proposed claim ("This drinking water is intended for use in the prevention of tooth decay disease"), your product would not be a drug under the Act unless there was other evidence to establish its status as a drug. As Ms. Billingslea discussed in her letter of August 7, your other proposed claim – "fluoride added" – would not render your product a drug. You can also reference Ms. Billingslea's letter for information about a health claim that may be used on certain bottled water products.

As Ms. Billingslea stated in her letter of August 7, we recommend that you contact Ms. Barbara Gould in CDER if you wish to market your bottled water product with your proposed claim about the prevention of tooth decay.

Patricia A. Hansen, Ph.D.


Acting Director
Office of Nutrition, Labeling and Dietary Supplements
CFSAN
FDA

Leigh Hayes


Product Assignment Officer
Office of Combination Products
FDA

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