

FLUORIDATION AND THE FDA CDER

FDA CDER HAS JURISDICTION FOR ARTIFICIAL FLUORIDATION

Since 2008 over 60 requests – FDA CDER response is “pending”

We are standing on the shoulders of many who have
lost their health and wealth fighting against fluoridation.

FLUORIDATION IS A DRUG

Bill Osmunson DDS, MPH

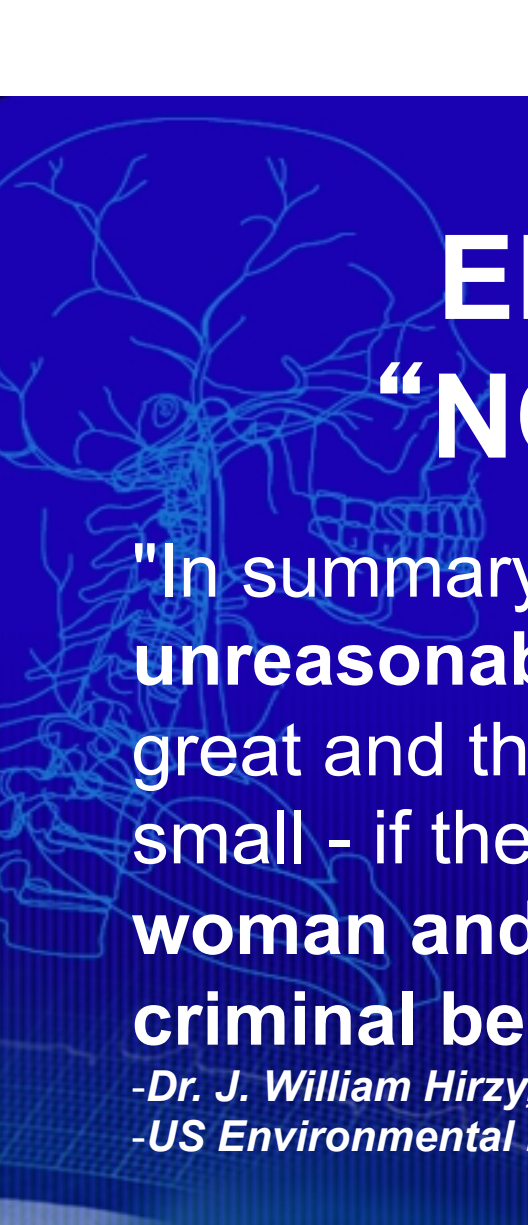
Aesthetic and Comprehensive Dentistry

Neuromuscular Dental Practitioner,

Educator, Author, and Nutritionist

www.IAOMT.org www.fluoridealert.org

www.slweb.org www.washingtonsafewater.com



EPA Scientists say “NO” to Fluoridation

"In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all – that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments."

*-Dr. J. William Hirzy, Senior Vice-President, Headquarters Union,
-US Environmental Protection Agency, March 26, 2001*

How Much Fluoride Should We Ingest?

“The recommended optimal fluoride intake for children to maximize caries prevention and minimize the occurrence of dental fluorosis is often stated as being 0.05-0.07 mg/kg/day (Levy 1994; Heller et al. 1999, 2000).

Burt (1992) attempted to track down the origin of the estimate of 0.05-0.07 mg/kg/day as an optimum intake of fluoride but was unable to find it.” NRC 2006 p 68.

Mother’s milk provides about 250 times less fluoride than formula made with water at “optimum” fluoride concentrations.

ADA recommends a TOTAL of 3 mg for women and 4 mg for men

"Hodge (1950) studied children consuming fluoride in their drinking water. Fluoride levels of 0-14 ppm were investigated. Dental mottling was the parameter of interest. Fluoride levels of 2-10 ppm produced a linear dose- response curve (increasing mottling with increasing dose). Fluoride levels of 0.1-1.0 ppm produced no observable effect. An assumption of 20 kg bw and 1 L/day water consumption for children was used, since the children studied were 12-14 years old. It is further assumed that a 20-kg child consumes 0.01 mg of fluoride/kg bw/day in the diet (50 FR 20164). Thus, a total intake would be approximately 0.06 mg/kg/day. "

<http://www.epa.gov/IRISsubst/0053.htm#orange>

- No observable adverse effect was desired.
- However: 41% of children now have dental fluorosis.

***NRC 2006, Too Much Fluoride
EPA responds proposing 33% MORE fluoride is safe
And still, all above the black line will ingest too much.***

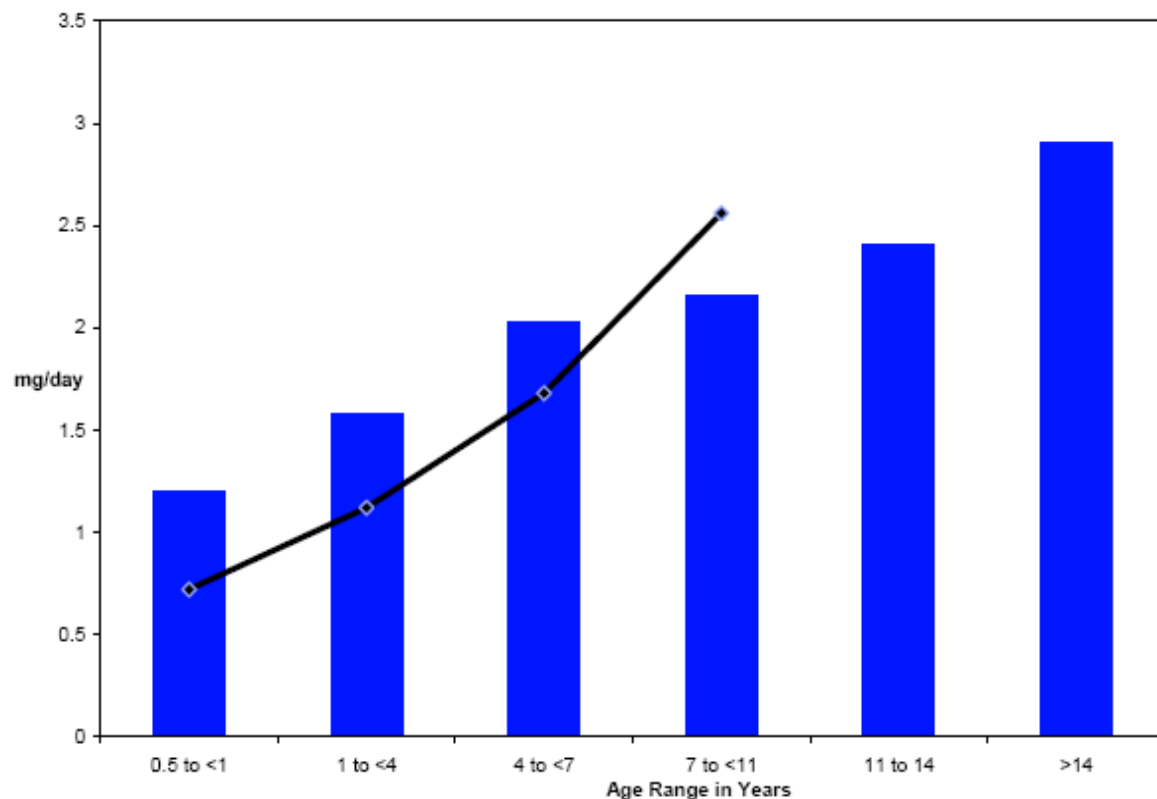


Figure 8-1. Total Daily Fluoride Intake Estimates Relative to the Proposed RfD Using 90th Percentile Drinking Water Intake Data for Consumers Only and the Mean Drinking Water Fluoride Concentration (0.87 mg/L)

1. Proposed RfD will be 0.08 mg/kg/day
2. Infants ignored.
3. 10% of people ignored



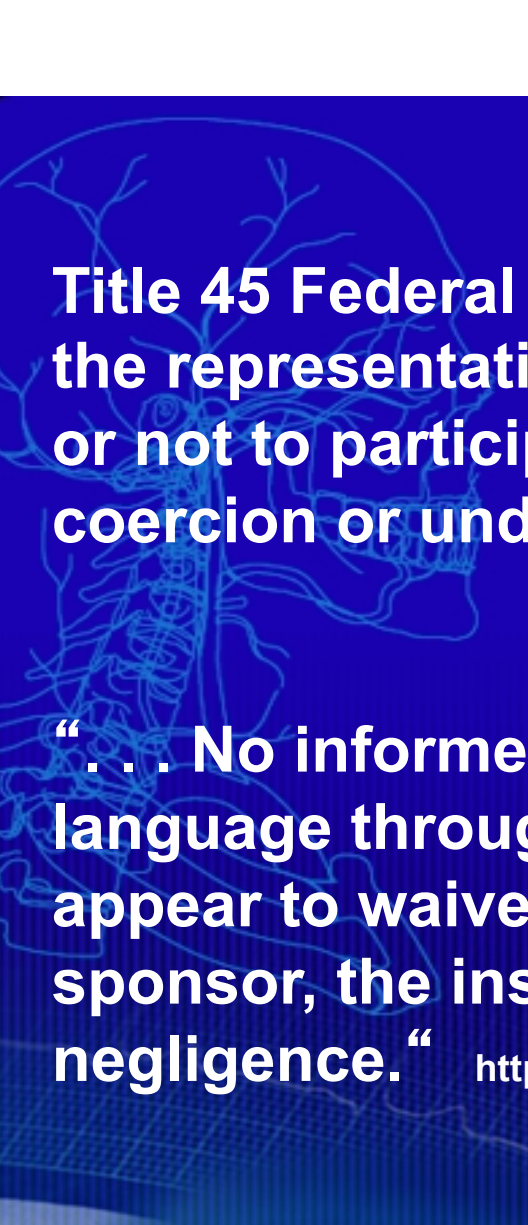
FLUORIDATION AND HHS

REASONABLE REQUESTS:

- 1. Instruct FDA CDER to no longer defer regulatory action. FDA CDER to send a letter to fluoridation manufacturers advising them to make FDA CDER NDA (New Drug Application) as required by Congress in the US FD&C Act.**
- 2. Instruct the CDC to stop the promotion (internet and education) of any and all drugs, including the ingestion of fluoride products, not FDA CDER approved.**

REQUESTS

- 3. Sponsor a review of the scientific evidence on fluoride's neurotoxicity by the National Academy of Science's National Research Council. The review should include studies listed at www.FluorideAlert.org/issues/health/brain**
- 4. Sponsor a quality published independent prospective randomized controlled trial (RCT), of the effectiveness of ingesting hydrofluorosilicic acid (fluoridation), including blood serum and urine concentrations of fluoride.**



Title 45 Federal Code “. . . provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”

“. . . No informed consent . . . may include any exculpatory language through which the subject . . . is made to waive or appear to waive any of the subject's legal rights. . . the sponsor, the institution or its agents from liability for negligence.” <http://www.washington.edu/research/hsd/hsdman4.html>

"As with any drug (or device), there may be unanticipated adverse effects."



Nuremberg Code

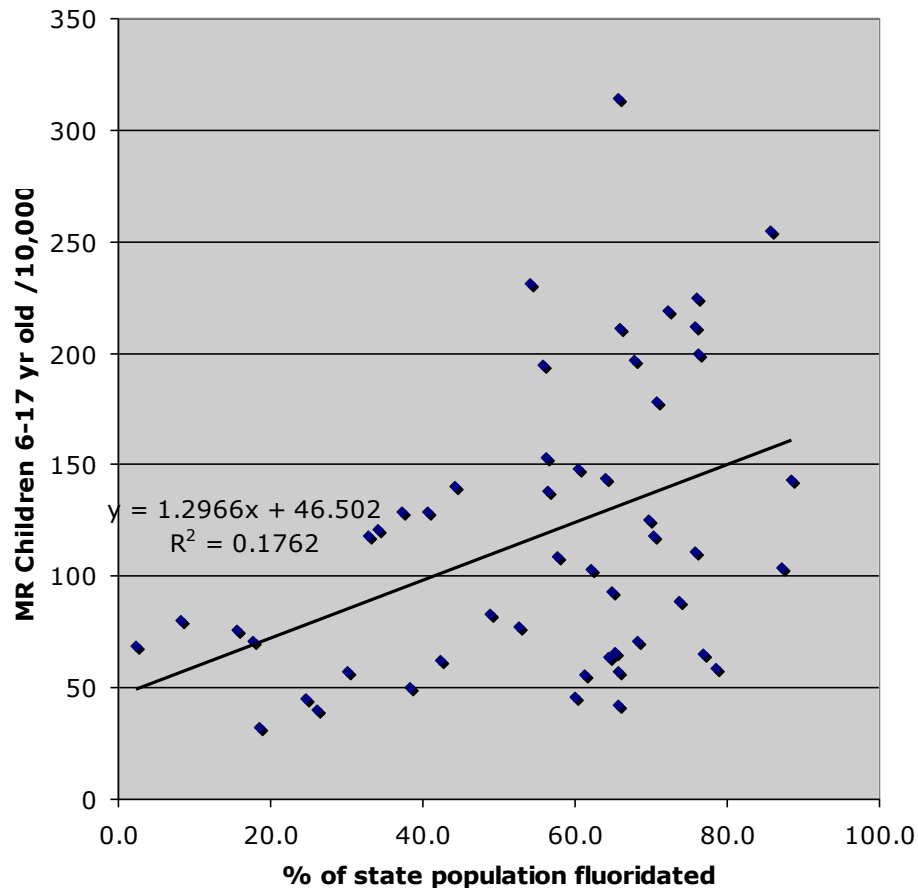
Prohibited Experimentation on patients without their Consent or Knowledge.

Human Subjects Review Committee

“Human subjects asked to contribute their time and effort to research should consent to do so freely. The consent should be given only after the subject understands what he or she is consenting to, and any risks that may be involved. Subjects should be assured that there will be no penalties for declining to participate, and that they are free to withdraw from the research at any time after they have given their initial consent.”

University of Washington <http://www.washington.edu/research/hsd/hsdman4.html>

**FLUORIDATION'S EFFECT ON MENTAL RETARDATION
1992**



**Triple the number of low IQ=
0.5 standard deviations=
8 IQ loss**

Confidence in this chart alone is low

**Add this to published studies and
And we should be seriously concerned**

<http://apps.nccd.cdc.gov/giscvh/map.aspx> <http://apps.nccd.cdc.gov/nohss/FluoridationV.asp>
<http://pubs.usgs.gov/circ/2004/circ1268/htdocs/table05.html> <http://www.cdc.gov/mmwr/preview/mmwrhtml/00040023.htm>

SODIUM FLUORIDE IS A HIGHLY TOXIC POISON

ORS 453.005 (8) “Highly toxic” means any substance that falls within any of the following categories:

(a) Produces death within 14 days in one-half or more of a group of 10 or more laboratory white rats each weighing between 200 and 300 grams, at a single dose of 50 milligrams or less per kilogram of body weight, when orally administered;”

About 5 mg/Kg of body weight of NaF is considered lethal for an adult.

Washington State Board of Pharmacy

“RCW 69.38.010

“Poison” defined.

As used in this chapter “poison” means:

- (1) Arsenic and its preparations;**
- (2) Cyanide and its preparations, including hydrocyanic acid;**
- (3) Strychnine; and**
- (4) Any other substance designated by the state board of pharmacy which, when introduced into the human body in quantities of sixty grains or less, causes violent sickness or death.”**

60 grains = 3,888 mg

15 mg NaF lethal for a child

“Not our baily wick. Not a drug. Not dispensed. Not a substance but a chemical. Dr. Osmunson do you know what you are doing?” 4/11/2008



FDA REGULATES SUBSTANCES WHICH TREAT **PEOPLE**
EPA REGULATES SUBSTANCES WHICH TREAT **WATER**

EPA determines safety of contaminants in **WATER**

CDC/HHS & Surgeon General & Public Health experts
Do not determine benefit versus risk.

FDA CDER weighs the evidence to determine
BENEFITS VS RISKS FOR MARKETING

The prescribing **doctor** is the patient's legal intermediary

The DEA regulates controlled substances (narcotics),
Not legend (prescription) drugs.

WHITENS TEETH & FRESHENS BREATH

Crest

FLUORIDE ANTICAVITY
TOOTHPASTE

NET WT
.85 OZ (24g)

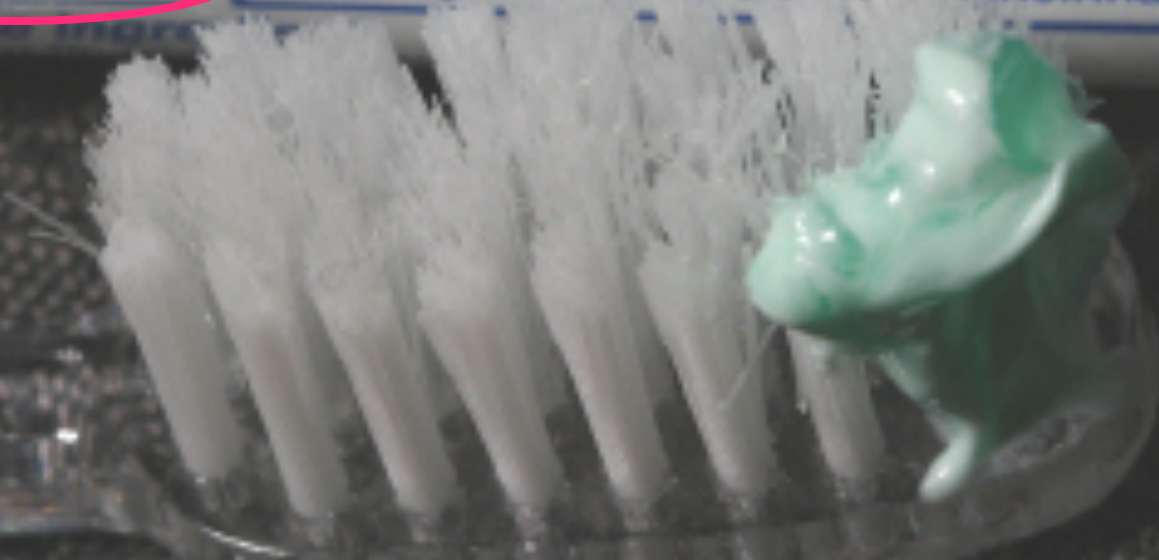
WHITE

PLUS
SO

Minty

Drug Facts

Dist. by Procter & Gamble Cincinnati OH 45202





Dave Kennedy DDS

“John Yiamouyiannis filed a petition to remove fluoride tablets (supplements) because they were not FDA approved back 30 years ago. The FDA did nothing which is to be expected. You have to follow the petition up with a lawsuit. By law FDA has to respond in 90 days. FDA will go to court and ask for an additional 90 days then do nothing. Unless you ask a court to force them to act they refuse.” Dave Kennedy DDS

“I recall New Jersey assemblyman John V. Kelly got excited and filed the appropriate notice about fluoride vitamins and tablets being unapproved back 20 years ago. . . The FDA did nothing” Dave Kennedy DDS



“NDA withdrawn for fluoride and vitamin combinations Drug Therapy June 1975

The FDA has addressed a “regulatory letter” to approximately 35 companies marketing combination drugs consisting of fluoride and vitamins. The letter states that these drugs are related to a product (Enziflur lozenges) for which FDA has withdrawn approval of a new drug application. The NDA for Enziflur was withdrawn because there is no substantial evidence of drug effectiveness as prescribed, recommended, or suggested in its labeling.

The FDA has therefore advised manufacturers of combination fluoride and vitamin preparations that their continued marketing is in violation of the new drug provisions of the Federal Food, Drug, and Cosmetic Act; they have, therefore, requested that marketing of these products be discontinued.”



Richard Sauerheber

“I have now submitted 58 letters to the FDA in support of the petition since 2010 on various topics. The FDA ruled that fluoridated water was not to be used in kidney dialysis units. . . . This was an important ruling.”



FDA CDER HAS JURISDICTION To weigh the **BENEFITS VS RISKS**

CONGRESS DEFINES **DRUGS**:

*“Articles intended for use in the
... prevention of disease ...”*

21 USC 321 (g)(1)(B)

**FDA testified to Congress that fluoride
is a drug.**

Congressional Investigation 2001



FDA Confirms: F- is an Unapproved Drug

“A search of the Drugs@FDA database . . . does not indicate that sodium fluoride, silicofluoride, or hydrofluorosilicic acid has been

approved . . .”2009 Best regards, Drug Information SH, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration

FDA CDER ADVISES: “Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers’ health at risk.”

<http://www.nabp.net/publications/assets/OR082008.pdf> Oregon Board of Pharmacy 8/08 Newsletter

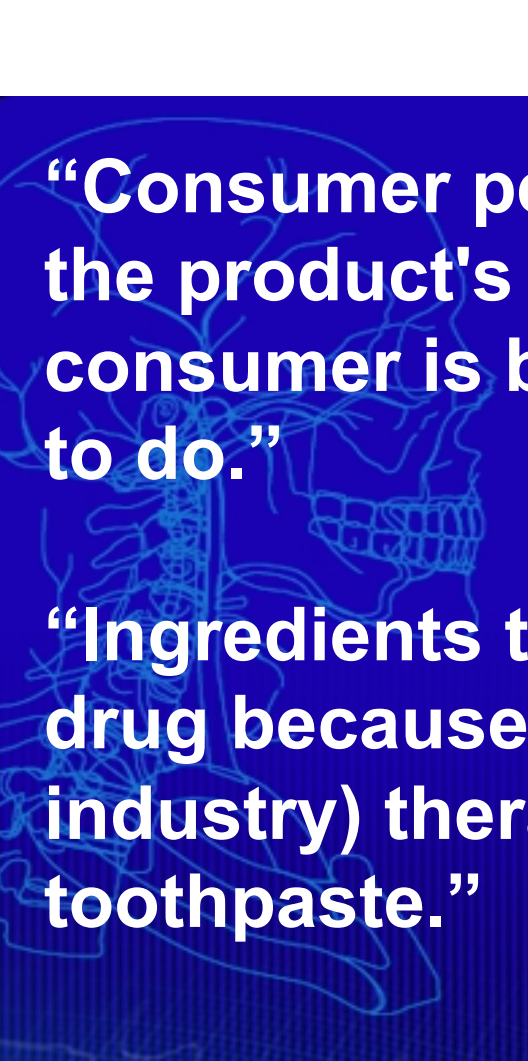
FDA GUIDANCE DOCUMENT

“The legal difference between a cosmetic and a drug is determined by a product's intended use. . .

The FD&C Act defines drugs, in part, by their intended use, as ‘articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease’ and ‘articles (other than food) intended to affect the structure or any function of the body of man or other animals’ [FD&C Act, sec. 201(g)(1)]. . . .

“Intended use may be established in a number of ways. Among them are:

Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. . . .”



“Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.”

“Ingredients that may cause a product to be considered a drug because they have a well known (to the public and industry) therapeutic use. An example is fluoride in toothpaste.” FDA GUIDANCE DOCUMENT

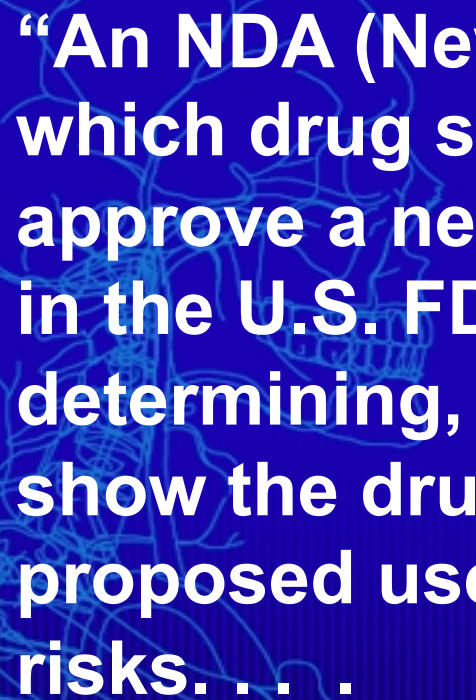
“INTENT OF USE” IS KEY.

Not dilution or even placebo exempts the substance.



“Drugs are subject to FDA approval.

Generally, drugs must either receive premarket approval by FDA or conform to final regulations specifying conditions whereby they are generally recognized as safe and effective, and not misbranded”.



“An NDA (New Drug Application) is the vehicle through which drug sponsors formally propose that FDA approve a new pharmaceutical for sale and marketing in the U.S. FDA only approves an NDA after determining, for example, that the data are adequate to show the drug's safety and effectiveness for its proposed use and that its benefits outweigh the risks. . . .

“A note on "new drugs": Despite the word "new," a "new drug" may have been in use for many years. If a product is intended for use as a drug, no matter how ancient or "traditional" its use. . . .”

“... the law requires strict adherence to GMP (Good Manufacturing Practices) requirements for drugs, and there are regulations specifying minimum current GMP requirements for drugs [Title 21 of the Code of Federal Regulations (CFR), parts 210 and 211]. Failure to follow GMP requirements causes a drug to be adulterated [FD&C Act, sec. 501(a)(2)(B)].

“... it is mandatory for drug firms to register their establishments and list their drug products with FDA [FD&C Act, sec. 510; 21 CFR 207].”

**US Food, Drug, and Cosmetics Guidance, Compliance and Regulatory Information can be found at:
<http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm>**



The Final Manufacturer of the fluoridated water drug are cities and water districts.

Fluoridated water is:

- **Adulterated = not manufactured in an FDA approved facility, GMP.**
- **Misbranded = NO label of cautions, warnings, dosage.**
- **Illegal = without NDA (FDA CDER APPROVAL)**
- **Manufacturer not registered with the FDA**



Fluoride is NOT a food.

- **The absence of fluoride does not cause any disease.**
- **No metabolic function requires fluoride**
- **Mother's milk usually contains no detectable fluoride.**
- **Fluoride in toothpaste is approved as a drug**
- **Fluoride fits within poison highly toxic laws; Exempt under drug laws or pesticide laws**



Fluoride is not a nutrient

“FDA wrote in the Federal Register in 1979 that all government documents were to remove reference to fluoride as a nutrient or probable nutrient because no deficiency state could be induced. . . .

the EPA and the ATSDR (Agency for Toxic Substances and Disease Registry) have developed toxicological profiles for it and they do not do that for nutrients only poisons. Dave Kennedy DDS



FDA determines:

Prescription drugs vs Over the counter drugs

**Drug Enforcement Agency (DEA) regulates
Controlled Substances (Narcotics)**

Fluoride is a Drug (ID AND WA BOP).

**State Courts so far have determined,
fluoridation is not a drug.**



Health Claim Notification for Fluoridated Water and Reduced Risk of Dental Caries

“ . . . a manufacturer may submit . . . a notification of a health claim based on an authoritative statement from an appropriate scientific body of the United States Government or the National Academy of Sciences (NAS) or any of its subdivisions.

<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073602.htm>

Recommendation for Using Fluoride to Prevent and Control Dental Caries in the U.S. (Centers for Disease Control, 2001):

"Widespread use of fluoride has been a major factor in the decline in the prevalence and severity of dental caries (i.e., tooth decay) in the United States and other economically developed countries. When used appropriately, fluoride is both safe and effective in preventing and controlling dental caries. . . ."

<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073602.htm>

The claim language is: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]." In addition, the health claim is not intended for use on bottled water products specifically marketed for use by infants.



The Courts

The Court ruled even under emergency conditions of war the Government cannot force an individual to be medicated with a substance which has not been specifically approved for the purpose and manor it is intended. Case regarding AVA, a non FDA approved anthrax drug. Doe v. Rumsfield 2003 U.S. Dist. LEXIS 22990

The FDA CDER has not approved any Fluoridation substance

WHERE DO WE GO FROM HERE?

- **Contact big chain pharmacies to no longer sell unapproved fluoride supplements.**
- **Tell your physician and Dentist you do not want fluoride products**
- **Report adverse drug reactions Online or Call FDA at 1-800-FDA-1088 or Form FDA 3500**
- **And if harmed, contact Chris Nidel chris@nidellaw.com
www.nidellaw.com**
- **FDA CDER NDA and Legal Action**
- **HHS petitions and Legal Action.**
- **Support FAN and Moms Against Fluoride**