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ELLIS ISLAND ADVISORY COMMITTEE

October 26, 2000

Commissioner Jane E. Henny, M.D.
U.S. Food and Drug Administration
5600 Fischers Lane
Rockville, Maryland 20857

Dear Commissioner Henny:

I am petitioning the FDA to remove unapproved children's fluoride supplements from the market. Section 505(d) of the Food, Drug and Cosmetic Act (FDC Act) 21 CFR part 314.50(d)(5) requires either a New Drug Application (NDA) or an Abbreviated New Drug Application to demonstrate the safety and effectiveness of a drug product prior to approval. Children's fluoride supplements for dental caries prevention are violative products. Recent studies have demonstrated clearly that not only are these products ineffective, but they actually contribute to dental fluorosis.

In 1992, the New Jersey Department of Health conducted a study suggesting a possible relationship between fluoridated water and osteosarcoma. The New Jersey study was undertaken because other studies had suggested a possible relationship between fluoride and osteosarcoma (Hoover 1991, National Toxicology Program 1990).1 New Jersey has little fluoridated water and consequently large numbers of infants and children are prescribed fluoride drops and tablets. In response to the New Jersey study, I filed a Freedom of Information Act request2 with the FDA to obtain copies of the studies the FDA had used in evaluating the safety and effectiveness of these products. I was shocked when the FDA informed me that the FDA had no such studies and that children's fluoride supplements were not approved.3

On June 3, 1993, I petitioned the FDA to remove these unapproved products from the market.4 On July 18, 1994, the FDA responded5 that a 1975 FDA Dental Drug Products Advisory Committee reported "that there is a medical rationale for appropriate vitamin/fluoride preparations." The Dental Committee unanimously decided to make the following recommendation for fluoride supplements for publication in the Federal Register, "Dietary supplements of sodium fluoride or acidulated phosphate fluoride in the form of tablets, lozenges or drops ...are safe and effective for the reduction of the incidence of dental caries". The committee minutes report, however, states "there is no evidence that the effect of fluoride is

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enhanced by combination with vitamins. Therefore, there is no satisfactory rationale for the use of these combinations." The draft minutes of the committee meeting of January 22, 1975 list no scientific references or rationale for any of their conclusions.<sup>6</sup> The committee produced no written report. The Federal Register notice was never published.<sup>7</sup>

I recognize that the FDA has approved NDAs for Over The Counter (OTC) topical fluoride products such as toothpaste. The Durham-Humphrey amendment of 1951 requires a prescription for a drug that cannot be safely used without medical supervision. The OTC data cannot be applied to systemic fluoride supplements which are prescription drugs.

In a letter to my office dated August 21, 2000, the FDA maintains that "fluoride tablet and drug products are not subject to new drug requirements since they are identical to fluoride drug products marketed prior to 1938."<sup>8</sup> Clearly, this is not the case. The FDA records show only that sodium fluoride in bulk form was available prior to 1938. The FDA has no record of use as tablets, drops or any therapeutic dosage form.<sup>9</sup> The only pre-1938 use of sodium fluoride my office has been able to identify was as a rodenticide and insecticide. The law requires that once a product is prepared in dosage form an NDA is required. Clinical trials of dietary fluoride supplements did not begin until the 1940's. The American Dental Association published its first recommendations for fluoride supplements in 1958.<sup>10</sup> The American Academy of Pediatrics followed with its own recommendations in 1972.<sup>11</sup> Clearly, these dosed prescription drugs for dental use are post-1938 products, thus requiring NDAs.

In 1999, a meta-analysis published in *Community Dentistry and Oral Epidemiology* confirmed "the use of fluoride supplements during the first six years of life is associated with a significant increase in the risk of dental fluorosis."<sup>12</sup> In another 1999 study published in the *Journal of Public Health Dentistry*, Dr. Brian Burt, who is recognized as one of the world's foremost authorities on fluoride supplements, states "the additional cariostatic benefits that accrue from using supplements are marginal at best, while there is a strong risk of fluorosis when young children use supplements."<sup>13</sup>

Parents are spending millions of dollars annually on products that have not been proven effective. They then have to spend millions more to repair the fluorosis caused by these products. Every health care dollar spent on ineffective drugs is one dollar less available for effective drugs. Thousands of pediatricians and dentists and millions of parents are under the false, but, logical impression that these prescription products are approved by the FDA as being safe and effective. To the best of my knowledge, neither the American Academy of Pediatrics, the American Dental Association, nor the American Academy of Pediatric Dentistry have ever advised their members that fluoride supplements are not FDA approved even though I requested they do so in 1993.<sup>14</sup> There could be serious legal and ethical ramifications for these uninformed professionals. I urge you to issue an advisory to these organizations to inform their membership that fluoride supplements are not FDA approved.

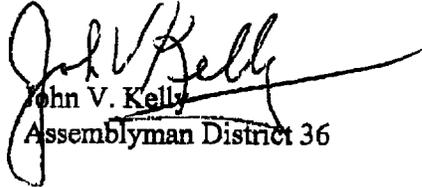
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The FDA is the only government agency with the authority under the FDC Act to declare medications safe and effective for human health. However, the reality is that the FDA has not seen an NDA for fluoride supplements in a quarter of a century. The last time the FDA reviewed an NDA for fluoride supplements was in 1975<sup>15</sup> and that NDA was rejected. The FDA has never approved any fluoride product as being safe and effective for internal use whether it be dental supplements or to treat osteoporosis.

Children today are at risk of overexposure from multiple fluoride sources in their dental products, diet and environment. The Physician's Desk Reference lists the following possible side effects from childrens fluoride supplements: black tarry stools, vomiting, diarrhea, drowsiness, shallow breathing, stomach cramps, tremors, weakness. While reports are not frequent, in the case of an unapproved drug for caries prevention, there can be no medical, legal or moral justification for putting any subset of the population at risk, particularly children.

The manufacturers of fluoride supplements have had fifty years to conduct clinical trials and toxicology studies to demonstrate the safety and effectiveness of systemic fluoride and submit them for FDA approval. They have not done so. Fifty years is a long time - even for the FDA.

Sincerely,

  
John V. Kelly  
Assemblyman District 36

JK/ki



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Commissioner Jane E. Henney, M.D.  
U.S. Food and Drug Administration  
5600 Fischers Lane  
Rockville, Maryland 20857

Dear Commissioner Henney:

As an addition to my October 26 letter petitioning the FDA to remove fluoride supplements from the market, I would like to add the following information:

ENVIRONMENTAL IMPACT STATEMENT

This petition provides for a general exclusion as noted in 21 CFR Part 25.30. Nothing requested in this petition will have an impact on the environment.

CERTIFICATION

I certify that, to the best of my knowledge and belief, this petition includes all information and views on which this petition relies.

Sincerely,

John V. Kelly  
Assemblyman District 36

JK/ki

REFERENCES

1. A Brief Report on the Association of Drinking Water Fluoridation and the Incidence of Osteosarcoma Among Young Males. Perry Cohn, Ph.D., MPH, NJ Department of Environmental Protection and NJ Department of Health, 1992.
2. John V. Kelly letter to FDA August 26, 1992.
3. FDA Office of Prescription Drug Compliance, Frank Fazzari, letter to John V. Kelly dated January 29, 1993.
4. John V. Kelly letter to FDA Commissioner David Kessler dated June 3, 1993.
5. FDA Center for Drug Evaluation, Dr. Janet Woodcock, to John V. Kelly dated July 18, 1994.
6. Draft minutes, FDA Bureau of Drugs, Dental Drug Products Advisory Committee, January 22, 1975.
7. FDA Office of Prescription Drug Compliance, Frank Fazzari, letter to John V. Kelly, January 28, 1993.
8. FDA Office of Prescription Drug Compliance, Sakineh Walther, letter to John V. Kelly, August 21, 2000.
9. FDA Center for Drug Evaluation, Office of Generic Drugs, Don Hare, facsimile to John V. Kelly dated October 20, 2000.
10. Overview of the History of Fluoride Supplementation Schedules, Journal of Public Health Dentistry, Volume 59, Number 4, page 252, Fall 1999.
11. Ibid.
12. Community Dentistry and Oral Epidemiology, Fluoride Supplements and Fluorosis: A metaAnalysis, Dr. Amid Ismail, 1999, Volume 27, pages 48-56.
13. Journal of Public Health Dentistry, The Case for Eliminating the Use of Dietary Fluoride Supplements for Young Children, Dr. Brian Burt, Volume 59, Number 4, Fall 1999, pages 269 - 274.
14. John V. Kelly letter to American Academy of Pediatrics, Dr. Howard Pearson, June 3, 1993.
15. FDA Office of Prescription Drug Compliance, Sakineh Walther, letter to John V. Kelly, August 21, 2000.