DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 15 2001

4578 '01 MAR 20 P4:37

The Honorable Phil Gramm
United States Senator
2323 Bryan Street #2150
Dallas, Texas 75201

Dear Senator Graham:

Thank you for your inquiry of January 18, 2001, on behalf of your constituent, Mr. Joe Landwehr of Abilene, Texas, regarding a citizen petition filed by New Jersey Assemblyman John V. Kelly, requesting the Food and Drug Administration (FDA or the Agency) to remove children's fluoride supplements from the market.

Assemblyman Kelly's petition was filed with FDA on November 6, 2000. In accordance with Title 21, Code of Federal Regulations, Section 10.30(d) (enclosed), under the Citizen Petition process, an interested person may submit written comments to the Dockets Management Branch for all submissions relating to a filed petition. These comments become part of the docket file and will be taken into consideration when making a final decision to the petition by FDA.
Mr. Landwehr's comments will be forwarded to the docket for submission.

Any further comments Mr. Landwehr may have regarding this petition can be forwarded to:

Department of Health and Human Services
Food and Drug Administration
Dockets Management Branch, room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857
Attention: Docket Number 00P-1602/CP1.

00P-1602

LET 1

Thanks again for contacting us concerning this matter. If we may be of further assistance, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch - HFA-305

[Code of Federal Regulations]
[Title 21, Volume 1, Parts 1 to 99]
[Revised as of April 1, 2000]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR10.30**]

[Page 85-87]

TITLE 21--FOOD AND DRUGS

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES--Table of Contents

Subpart B--General Administrative Procedures

Sec. 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with Sec. 10.20 and in the following form:

(Date)_____

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

Citizen Petition

The undersigned submits this petition under ------ (relevant statutory sections, if known) of the ------ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to ------ (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any

[[Page 86]]

other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A) Claim for categorical exclusion under Secs. 25.30, 25.31, 25.32, 25.33, or Sec. 25.34 of this chapter or an environmental assessment under Sec. 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature)_____

(Name of petitioner)_____

(Mailing address)_____

(Telephone number)_____

(c) A petition which appears to meet the requirements of paragraph (b) of this section and Sec. 10.20 will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Dockets Management Branch on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) Except as provided in paragraph (e)(4) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

1904 N 5th Street
Abilene, Tx 79603

January 6, 2001

Senator Phil Gramm
370 Russell Senate Office Building
Washington, DC 20510-4302

JAN 16 2001

Dear Senator Gramm:

I am writing you with an issue of concern that I would like you to address.

I am enclosing a copy of a letter from New Jersey Assemblyman, John Kelly to Jane Henny, Commissioner of the US Food and Drug Administration. Assemblyman Kelly is petitioning the FDA to remove children's fluoride supplements from the market. His plea is predicated on the fact that after 50 years of being on the market, fluoride supplements are still classified by the FDA as unapproved drugs, and in fact, have never undergone the rigorous tests for safety and effectiveness ordinarily required of all prescription drugs by the federal government.

I am writing to ask that you and your staff research this issue, and join Assemblyman Kelly in pressuring the FDA to either do its job in requiring the necessary tests of fluoride supplements, or removing these unproven products from the market. Since children in Texas are being exposed to these products, I am assuming that this matter would also be of concern to you. I would appreciate it if you could also pass this information on to the appropriate committee chairman in the senate, and report back to me on the action you have taken.

I appreciate your prompt attention to this matter.

Sincerely,

Joe Landwehr

PS If you wish to respond to this letter electronically, my email address is eyeofcentaur@earthlink.net.

01-549

NEW JERSEY GENERAL ASSEMBLY

JOHN V. KELLY
ASSEMBLYMAN, 36TH DISTRICT
BERGEN-ESSEX-PASSAIC COUNTIES
871 FRANKLIN AVENUE, 2ND FLOOR
NUTLEY, NJ 07110
(973) 667-6123
FAX (973) 667-9614

COMMITTEES
CHAIR
HOUSING COMMITTEE
NEW JERSEY FIRE SAFETY COMMISSION
MEMBER
APPROPRIATIONS COMMITTEE
GOVERNOR'S LANDLORD-TENANT TASK FOR
ELLIS ISLAND ADVISORY COMMITTEE

October 26 2000

JAN 16 2001

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). 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 request 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 responded *5* 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 Kelly page 2 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.*6* The

committee produced no written report. The Federal Register notice was never published. *7*

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."*8* 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.*9* The only pre-1938 use of sodium fluoride my office has been able to identify wâs 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. *10* The American Academy of Pediatrics followed with its own recommendations in 1972. *11* Clearly, these dosed prescription drugs for dental use are post-1938 products, thus requiring NDAs.

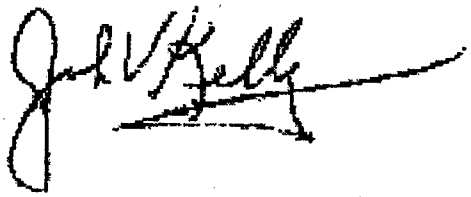
In 1999, a meta-analysis published in Community Dentistry and Oral Epidemiology confirmed "the use of fluoride supplements during the first six years of life is associated with a significant increase in the risk of dental fluorosis." *12* In another 1999 study published in the Journal of Public Health 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." *13*

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. *14* 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.

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 *15* 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

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.

2. John V. Kelly letter to FDA August 26, 1992.

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Phil Gramm
Texas

United States Senate

MEMORANDUM

Date: 1-18-01

Food and Drug Administration
Office of Legislative Affairs
5600 Fishers Lane
Rockville, Maryland 20857

A constituent has sent the enclosed communication. A response which addresses his/her concerns would be appreciated.

Please send your response, together with the constituent's correspondence, to the following address:

Office of Senator Phil Gramm
2323 Bryan Street, #2150
Dallas, Texas 75201

Attention: Richard Zientek
(214) 767-5217
(214) 767-8754 (fax)

email: Richard_Zientek@gramm.senate.gov

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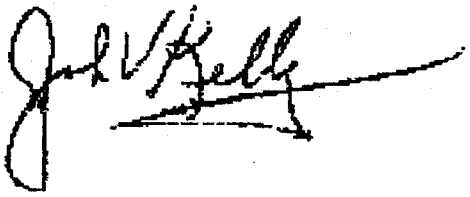

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Assemblyman District 36

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