DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

NOV 17 2005

Mr. Daniel G. Stockin
Dr. Lillie B. Fessenden
The Lillie Center, Inc.
P. O. Box 1951
Brentwood, Tennessee 37024

Dear Mr. Stockin and Dr. Fessenden:

This is in response to your letter of August 17, 2005 to the Food and Drug Administration (FDA or agency) concerning fluoride-containing supplements. Below, we respond to the three specific questions you posed to the Agency.

1. Have any fluoride supplements ever been approved by the FDA?

No. To date, FDA has approved no fluoride-containing supplements as prescription or over-the-counter drugs. Dietary supplements do not require premarket approval by FDA.

2. Is it true that the FDA in the 1970's asked fluoride supplement manufacturers to remove fluoride supplements from the market?

In 1974, the Commissioner of Food and Drugs concluded that it was in the interest of the public health to limit the addition of fluorine compounds to foods to that resulting from fluoridation of public water supplies, bottled water and residues of the insecticidal fluorine compounds cryolite and synthetic cryolite (sodium aluminum fluoride) on specific agricultural commodities. This decision is contained in the agency's regulations at 21 CFR § 170.45.

However, the 1976 Proxmire Amendment (section 411 of the Federal Food, Drug, and Cosmetic Act (the act) prohibits FDA from setting maximum limits on the potency of vitamins and minerals sold as dietary supplements and from classifying them as drugs solely because of high potency. Further, the Dietary Supplement Health and Education Act of 1994 (DSHEA) exempts dietary supplement ingredients from consideration under the food additive provisions of the act (see Section 201(s)(6) of the act). Accordingly, a dietary supplement containing fluoride is lawful for sale in the United States if it does not present a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use (see Section 402(f)(1)(A) of

the act); if it is not otherwise adulterated under any other provision of Section 402 of the act; if it is not misbranded under section 403 of the act; and not an unapproved new drug under the act or an adulterated or misbranded drug. At this time, FDA has not concluded that any dietary supplement containing fluoride violates the act.

3. If fluoride supplements have not been approved, why is FDA allowing them to be prescribed today by dentists?

Dietary supplements do not require premarket approval by FDA. Accordingly, unless determined to be adulterated or misbranded or otherwise in violation of the act (as described above), FDA has no legal authority to preclude the marketing of dietary supplements containing fluoride.

There are no approved New Drug Applications (NDAs) on file with FDA covering fluoride supplements for infants that may be marketed as prescription or over-the-counter drugs. However, at a meeting of the FDA's Dental Drug Product Advisory Committee on January 22, 1975 (copy enclosed) it was unanimously recommended to publish in the Federal Register (FR) the conditions under which supplements of sodium fluoride or acidulated phosphate fluoride would considered safe and effective. These conditions are described in Appendix I of the January 22, 1975 meeting minutes. Even though an FR notice was not published, as a matter of policy, the FDA has used, in part, the committee's recommendations to evaluate these kinds of products.

Accordingly, if these products are marketed in accordance with the conditions described in Appendix I and also meet the conditions described in Compliance Policy Guide 7132c.02, Marketed New Drugs Without Approved NDAs or ANDAs (Abbreviated New Drug Applications) (copy enclosed), the FDA does not currently object to the marketing of these products.

We hope that this satisfactorily responds to your questions.

Sincerely yours,

Robert J. Moore
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Center for Food Safety
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Enclosures