FDA U.S. FOOD & DRUG ADMINISTRATION

NOV 2 9 2016

Michael Connett, Esq.
Executive Director
Fluoride Action Network
3454 Vinton Ave.
Los Angeles, CA 90034

Re: Docket No. FDA-2016-P-1288

Dear Mr. Connett:

This letter responds to your citizen petition received by the Food and Drug Administration (FDA or Agency) on May 16, 2016 (Petition). The Petition requests that the Commissioner issue a notice of the FDA's intent to take enforcement actions (including seizures, injunctions, civil penalties, and/or criminals sanctions) against any and all companies that manufacture, distribute, and/or otherwise introduce into interstate commerce unapproved sodium fluoride-containing drops, tablets, and lozenges intended for dental caries prevention (Petition at 4).

More specifically, your Petition states that on January 13, 2016, FDA issued a warning letter to Kirkman Industries, Inc. (Kirkman), requesting that the company discontinue marketing all of the unapproved prescription drugs manufactured at the facility (Petition at 2). The unapproved prescription drugs involved in the Kirkman warning letter include sodium fluoride-containing drops and tablets intended to help prevent dental caries. In your Petition, you commend FDA's decision to issue the warning letter to Kirkman, and request that FDA "not limit its enforcement action against fluoride supplements to only Kirkman, as there are other, larger companies…that are manufacturing and distributing identical fluoride supplements" (Petition at 2). Your Petition argues that these types of fluoride-containing products are unapproved new drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and that these products are also ineffective at preventing dental caries and can have dangerous side effects (Petition at 2-4).

Decisions with respect to initiating enforcement action are generally made on a case-by-case basis and are within the discretion of the Agency.[1] Section 10.30 of FDA's regulations (21 CFR 10.30) generally governs the submission and review of citizen petitions. Per § 10.30(k), § 10.30 does not apply to "the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence . . . ." Agency decisions to take enforcement action are decisions related to the referral of a matter to a United States attorney for the initiation of court enforcement action for violations of the FD&C Act. Accordingly, requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition

[1] Courts have long recognized that they lack jurisdiction to enjoin FDA from initiating enforcement proceedings under the Act or to review agency decisions not to exercise its enforcement authority. *See Heckler v. Chaney*, 470 U.S. 821 (1985); *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 600-601 (1950).

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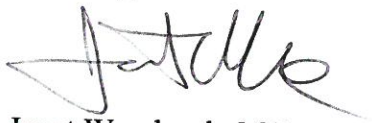
procedures, and this request is not an appropriate request for a citizen petition. Therefore, the petition is denied.

We nevertheless appreciate the information you provided. This type of information is often helpful for us to identify problems with marketed products and possible violations of the laws and regulations that we enforce. We take complaints seriously, and we will evaluate this matter to determine whether follow-up action is appropriate.

Sincerely,



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