Dr. Richard Sauerheber
Palomar College
1140 Mission Rd.,
San Marcos, CA 92069
February 11, 2016

Jeffrey Kightlinger and the Metropolitan Water District Board
Los Angeles, CA

Dear President Kightlinger and the MWD Board,

The many letters sent to you since 2007 on fluosilicic acid infusions MWD performs in public water supplies for the Los Angeles area basin have not been made clear. This letter serves to do that.

The U.S. Food and Drug Administration Criminal Investigations division is in the process of halting the sale of fluoride compounds intended for ingestion without a prescription. The FDA has also placed a written notice on details of the Federal laws being violated by those who supply fluoride compounds for ingestion without a prescription. These laws include provisions in the Food Drug and Cosmetic Act (henceforth, the Act).

The crux of the FDA criminal division action is that fluoride intended for ingestion requires not only 1) a prescription, but also 2) proper dosage instructions, and 3) proper public labeling. Laboratories that manufacture fluorides intended for ingestion are now being reprimanded for not labeling the materials "for prescription only" or "Rx only." And no fluoride compound is permitted to be ingested by children under age 3. Also, the ONLY fluoride material that is allowed to be swallowed are fluoride mouth rinses specially formulated for use ONLY under the direct supervision of health professionals and are NOT to be provided to the general public.

MWD disseminates fluoride into public water supplies intended to be consumed by all ages of children, which is a violation of 21CFR 355.60. MWD disseminates fluoride into public water supplies intended to be consumed without prescriptions, which violates section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)]. MWD disseminates fluoride into public water without proper dosage instructions that must accompany prescriptions for any need, which violates Section 502(f)(l) of the Act [21 U.S.C. 352(f)(1)].

Fluoride for oral ingestion is not recognized as safe and effective under conditions of improper labeling. In light of its toxicity and potential for harmful effects with the method of use, they are not safe for use except under the supervision of a licensed practitioner. Because fluoridation is intended for consumers that are not amenable to self-diagnosis and treatment by those who are not medical practitioners themselves, adequate directions cannot be written so that a layman can use them safely.

The labeling of fluosilicic acid by MWD of this unapproved prescription drug product fails to bear adequate directions for intended use. This causes fluosilicic acid infused by MWD to be misbranded under section 503(b)(4)(A) of the Act [21 U.S.C. 353(b)(4)(A)]. .

The forced addition of any chemical substance, including fluoride, into public drinking water (not required to sanitize the water) is a Federal offense. *It is absolutely necessary for MWD to halt fluosilicic acid dissemination for fluosilicic acid fluoride into public water supplies.* In addition, the interstate commerce for this material from your supplier fails to bear the "Rx only" symbol, which violates section 301a of the Act 21USC 3331(a).

Please understand that the Governor of Michigan is expected to be terminated from public office due to the attempt to save money by supplying corrosive-laden water to the city that coursed through pure lead pipes as service lines. Criminal charges are expected to be filed for some officials who have no protection from collection of personal assets.

The U.S. Congress is now examining the mechanism by which corrosives leach lead from plumbing. The attached reference explains this, where chloramines plus silicic acid from fluosilicic acid, at levels widely used to "fluoridate" water supplies, cause lead leaching from lead salts in various plumbing fixtures including brass, in addition of course to lead piping such as are found in many older homes, not only in the Eastern U.S., but also in Los Angeles and North San Diego County that MWD serves.

For all other Federal violations that MWD is committing by infusing fluoride compounds into public water supplies, please consult the attached FDA letter.

Thank you,

Richard Sauerheber, Ph.D. Chemistry

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Avenue SE, Suite 210
Bothell, WA 98021

Telephone: 425-302-0340
FAX: 425-302-0402

January 13, 2016

OVERNIGHT DELIVERY
SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 16-07

David K. Humphrey
Chief Executive Officer and President
Kirkman Laboratories, Inc.
10639 Professional Circle
Reno, Nevada 89521

WARNING LETTER

Dear Mr. Humphrey:

The United States Food and Drug Administration (FDA) conducted an inspection of your drug manufacturing facility, Kirkman Laboratories, Inc., located at 6400 Rosewood St., Lake Oswego, Oregon on June 3, 2015, through June 24, 2015. This inspection revealed that your firm is marketing the following unapproved new drugs: Kirkman Laboratories, Inc. Flura-Drops ® Sodium Fluoride drops, 2.21 mg; Perry Medical Fluorabon Drops USP; Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets; and Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets, in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 355(a)]. Additionally, FDA has determined that these products are misbranded drugs in violation of section 502 and 503 of the Act [21 U.S.C. §§ 352 and 353], as detailed below.

A. Unapproved New Drug Violations

Based on the information collected during the recent inspection, you manufacture and/or distribute unapproved new drugs in violation of sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)].

The unapproved new drugs include, but are not limited to:

- Kirkman Laboratories, Inc. Flura-Drops® Sodium Fluoride Drops, 2.21 mg (NDC 58223-517), which is labeled "for once daily, self-administered, systemic use as a dental caries preventive in pediatric patients";
- Perry Medical Fluorabon Drops USP, 0.25mg (NDC 11763-524), which is labeled "as an aid in the prevention of dental caries";
- Kirkman Laboratories, Inc. 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-678), which is labeled "as an aid in the prevention of dental caries"; and
- Kirkman Laboratories, Inc. 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-679), which is labeled "as an aid in the prevention of dental caries."

The above products are drugs within the meaning of section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. Further, as labeled, these drugs are "new drugs" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in their labeling. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the drug. There are no FDA-approved applications on file for the drugs listed above. The marketing of these drugs, or other new drugs, without an approved application constitutes a violation of the Act.[1]

B. Misbranding Violations

The above products also are "prescription drugs" as defined in section 503(b)(1)(A) of the Act [21 U.S.C. § 353(b)(1)(A)], because, in light of their toxicity or potential for harmful effects, or the method of their use, or the collateral measures necessary for their use, they are not safe for use except under the supervision of a practitioner licensed by law to administer them.[1]

Because these prescription drug products are intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for them so that a layman can use them safely for their intended uses. Consequently, the labeling of your firm's unapproved prescription drug products fails to bear adequate directions for their intended uses, causing them to be misbranded under section 502(f)(l) of the Act [21 U.S.C. § 352(f)(1)]. Because your drugs lack required approved applications, they are not exempt under 21 CFR 201.115 from the requirements of section 502(f)(1) of the Act. The above products also are misbranded under section 503(b)(4)(A) of the Act [21 U.S.C. § 353(b)(4)(A)], because the labels fail to bear the symbol "Rx Only." The introduction or delivery for introduction into interstate commerce of these drugs therefore violates sections 301(a) of the Act [21 U.S.C. § 331(a)].

C. Conclusions

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal actions without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. You should discontinue marketing all of the unapproved prescription drugs manufactured at your facility immediately. Additionally, FDA may withhold approval of requests for export certificates or approval of pending new drug applications listing your facility as a manufacturer until the above violations are corrected. A re-inspection may be necessary to verify corrective actions have been completed.

FDA requests that you contact CDER's Drug Shortages Staff immediately at drugshortages@fda.hhs.gov so that we can work with you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture, as required under 21 U.S.C. § 356c(a), and to allow FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Please notify this office in writing within fifteen (15) working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any documentation demonstrating that corrections have been made. If you no longer manufacture or market your fluoride products, your response should indicate, including the reasons that, and the date on which, you ceased production.

Your reply should be sent to the following address: U.S. Food and Drug Administration, 22215 26th Avenue SE, Suite 210, Bothell, Washington 98021 to the attention of Maria P. Kelly-Doggett, Compliance Officer. If you have any questions regarding any issues in this letter, please contact Compliance Officer Maria Kelly-Doggett by telephone at 425-302-0427.

Sincerely,
/S/
Miriam R. Burbach
District Director

cc: Lawrence A. Newman
Chief Operating Officer Technical & Regulatory Affairs
Kirkman Laboratories, Inc.
6400 Rosewood St.
Lake Oswego, Oregon 97035

1 Over-the-Counter (OTC) fluoride dentifrice drug products are subject to the final rule for Anticaries Drug Products for OTC Human use found in 21 CFR 355. As described in 21 CFR 355.60, the professional labeling allows for anticaries fluoride treatment rinses that are specifically formulated so they may be swallowed (fluoride supplements) and are provided to health professionals (but not to the general public) to contain additional dosage information. This additional information cannot be directed to consumers and the product must be in accordance with 21 CFR 355.60. The Flura-Drops® Sodium Fluoride Drops, 2.21 mg (NDC 58223-517), Fluorabon Drops USP, 0.25mg (NDC 11763-524), 1.1 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-678), and 2.21 mg Cherry Dye-Free Sodium Fluoride Tablets (NDC 58223-679) labels and labeling do feature additional dosage information (i.e., professional labeling information) and as such, the information is inappropriately directed to consumers. Additionally, 21 CFR 355.60 only allows additional dosage information for children 3 to under 14 years of age. These products all indicate for use down to age 6 months. Furthermore, a fluoride tablet is not a dosage form permissible under the final rule.