U.S. FOOD & DRUG ADMINISTRATION

APR 07 2017

FDA REQUESTED RECALL

Jay Borneman, Chief Executive Officer
Standard Homeopathic Company, Inc.
1165 E. 230 Street
Carson, CA 90745

Dear Mr. Borneman:

The Food and Drug Administration (FDA) is requesting that you immediately initiate a recall of all lots of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets, within expiry.

This request is based on FDA's inspection of your facility in Los Angeles, CA beginning September 20, 2016, and analytical findings of belladonna alkaloids in the Standard Homeopathic Company products that vary widely from the claimed content in the labels for these products, including tested content that far exceeded the label claim for the Hyland's Baby Teething Tablets and the Hyland's Baby Nighttime Teething Tablets. This variability in belladonna alkaloid concentrations indicates a fundamental lack of control over the content of toxic chemicals in your drugs.

We acknowledge receipt of your letter on October 5, 2016, of your decision to cease producing and selling these homeopathic teething products and your commitment to cease domestic shipment of these teething products no later than Friday, October 7, 2016. However, that does not address those products that are still available for sale and products already in distribution. On January 25, 2017, we contacted you to convey our serious concerns with your homeopathic teething products that remain on the market and asked what you intended to do regarding those products. We acknowledge receipt of your letter on January 26, 2017, in response to the January 25, 2017 phone call, in which you declined to take action on those products and stated your belief "that the public is amply protected."

During FDA's inspection of your facility, investigators identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause the Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething tablets to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP. In addition, under section 502(a) of the Act [21 U.S.C. §352(a)], a drug is misbranded if its labeling is false or misleading in any particular. FDA's test results on samples of Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets indicate alkaloid content that widely varies from the content stated on the product label, including alkaloid content that far exceeded the label claim of alkaloids for Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets. These products are misbranded under section 502(a) of the Act because the quantity of belladonna alkaloids listed on the label does not accurately reflect the quantity of belladonna alkaloids found in the tablets analyzed by FDA.

The FDA has determined that the inconsistent amounts of belladonna alkaloids found in these products produced by Standard Homeopathic Company represent a serious health hazard. Pharmacologic response to belladonna in the target population for these products is unpredictable and puts them at unnecessary risk as the ability of infants to

metabolize and eliminate belladonna alkaloids is impaired due to the complex development of hepatic enzymes and non-linear maturation of renal function. FDA action is necessary to protect the public health and welfare. FDA continues to review data and information related to these products as they become available. FDA will classify this FDA requested action as a Class I recall. A Class I recall represents a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. FDA recommends level A (100%) effectiveness checks be performed to the retail level.

FDA's recall policy and guidance is found in Title 21 Code of Federal Regulations (CFR), Part 7. FDA's Los Angeles District Office will provide guidance in implementing and assuring the effectiveness of your recall of these products, including reviewing the proposed recall communication to your consignees. We are requesting that you work closely with the district office and that you provide any necessary information regarding the recall in a timely manner. Title 21 CFR, Part 7 provides for, among other things, publishing your recall in an upcoming issue of the weekly FDA Enforcement Report.

Please respond to this letter by 5:00pm on April 10, 2017. Your response to this letter should be directed to:

CDR Steven E. Porter, District Director
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612-2445
Phone (949) 608-4448, Fax (949) 608-4415

Due to the seriousness of this situation, FDA is issuing a public communication today. The communication will notify consumers and retailers about the FDA Requested Recall letter and warn consumers and retailers to discontinue use or sale of these products due to the health risk associated with the use of these products.

Failure to comply with this request can result in further regulatory action being taken against you, your firm, and the adulterated products distributed by your firm.

Sincerely,

Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs