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MEMORANDUM

ATTORNET-CLIENT PRIVILEGED

TO: AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

FROM: ALVIN J. LORMAN, ASSOCIATION COUNSEL

DATE: NOVEMBER 15, 2021

SUBJECT: FDA DOCUMENTS ON COUGH/COLD PRODUCTS AND ANNUAL REPORTING

The Food and Drug Administration recently released two documents of interest to manufacturers and distributors of homeopathic drugs. The first was a "consumer update" concerning the use of cough/cold products in young children which specifically called attention to the fact that homeopathic products have never been reviewed by the agency for safety and efficacy. The second document discussed a new requirement for reporting of annual manufacturing data by all drug manufacturers. These documents are discussed below.

FDA "CONSUMER UPDATE" ON COUGH/COLD PRODUCTS FOR CHILDREN

On Oct. 28, 2021, FDA posted to its web site a "consumer update," "Should You Give Kids Medicine for Coughs and Colds?" (Available here: https://www.fda.gov/consumers/consumer-updates/should-you-give-kids-medicine-coughs-and-colds). The document states that "most children will get better on their own, and cough or cold medicine will not change the natural course of a cold or make it go away faster." FDA warned that it doesn't recommend OTC medicines for cough and cold symptoms in children younger than 2 because they may cause "serious and potentially life-threatening effects." The agency also notes that manufacturers voluntarily label these products as follows: "Do not use in children under 4 years of age."

FDA states, under a bold type headline, "There Are No FDA-Approved Homeopathic Products." FDA claims that despite labeling of these products as containing highly diluted substances, the agency "has found that some of these products contain active drug ingredients in levels that far exceed the amount stated on the product's label, and could cause significant harm to children." FDA goes on to state:

> "There are no FDA-approved homeopathic products, and homeopathic products sold in the U.S. have not met the FDA's requirements for safety and effectiveness. The FDA is not aware of any proven benefits of these products and urges you *not to give homeopathic cough and cold medicine to children younger than 4."*
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> "In certain instances, children younger than 4 who took these products have experienced serious side effects, some of which required hospitalization, including:
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> - Seizure, allergic reaction, and difficulty breathing.
> - Low blood potassium and low blood sugar, which may result in headache, crankiness, drowsiness, and weakness."
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> "These serious side effects occurred soon after children took a homeopathic cough and cold product; however, it is not always possible to know whether a reported side effect was caused by a medicine."

The Consumer Healthcare Products Association, representing the manufacturers of allopathic OTC cough/cold products, has, as of this date, determined not to issue a reply to FDA's statement.

The AAHP does not plan a proactive response to the FDA statement. AAHP members who label their cough/cold products for children below age 4 should be aware of the potential additional regulatory risk posed by these products.

DRAFT GUIDANCE: ANNUAL REPORTING OF QUANTITY OF LISTED DRUGS MANUFACTURED

On Oct. 29, 2021, FDA released a draft guidance document entitled, "Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act" (Available here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reporting-amount-listed-drugs-and-biological-products-under-section-510j3-federal-food-drug-and). The draft guidance notes that Section 3112(e) of the CARES Act requires that each person (including repackers and relabelers) who registers with FDA under section 510 of the FD&C Act with regard to a drug must report to FDA annually on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

This is a new annual requirement, and FDA noted that the requirement specifically includes homeopathic drugs (all homeopathic drugs should be listed pursuant to Section 510 of the Drug Listing Act). This is an annual reporting requirement, and the first reports are due soon. FDA said that, "Reports for calendar year 2020 should be submitted no later than Feb. 15, 2022, and reports for calendar year 2021 should be submitted no later than May 16, 2022. Reports for subsequent calendar years should be submitted no later than Feb. 15 of the following calendar year".

FDA's draft guidance provides the information you need to comply with this new requirement.