U.S. FOOD & DRUG ADMINISTRATION

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

JUN 30 2017

Dear Representative Pallone:

Thank you for your letter of December 20, 2016, regarding the safety of imported cosmetics. The Food and Drug Administration (FDA or the Agency) shares your interest in helping to ensure the safety of cosmetic products used by American consumers.

In your letter, you asked about imports of personal care products. The Federal Food, Drug and Cosmetic (FD&C) Act does not include a definition of "personal care products." People often use the term "personal care products" to refer to a wide variety of items that can include cosmetics, certain devices, and non-prescription drugs, which are regulated by FDA, and some products regulated by the Consumer Product Safety Commission that are intended for personal care. By agreement with your staff, this response provides data on imported cosmetics.

By way of background, all imported products regulated by FDA are required to meet the same FDA requirements as domestic products. Articles offered for import must comply with applicable laws and regulations at the time of entry to the United States. If a product is, or appears to be, among other things, adulterated or misbranded at the time of entry to the United States, it is subject to refusal of admission.

Cosmetic imports, by volume, are one of FDA's larger categories of imports, consisting of more than 2.9 million entry lines[1] in Fiscal Year (FY) 2016, yet the Agency's cosmetics program is one of its smallest. Not only is the volume of cosmetic imports quite significant, but many different countries and manufacturers export cosmetics to the United States. FDA has limited resources to examine imported cosmetics.

In response to your request, we have compiled data related to recent years of cosmetic imports, including information on the volume of such imports, FDA's efforts to screen those products, and problems identified as a result of our screening. We have restated your specific requests for information below in bold type below, followed by our responses.

1. The number and kinds of personal care products imported each year.

[1] An import entry can consist of one or multiple products. When multiple products are included under the same entry number, each product will be identified as a separate "line" or "entry line" under that entry.

In FY 2016, 2.9 million lines of cosmetics entered the United States through the FDA import process. Taken together, these imports represent virtually every type of cosmetic marketed in this country, including lipsticks, eyeliners, nail polish, face powders, tattoo inks and more. In FY 2016, 181 different countries were declared as the origin of cosmetics imported into the United States.

The lines of cosmetic imports entering this country have doubled over the last ten years, and there has been a steady and substantial increase in cosmetic imports each of the past five years. There were over 800,000 more import lines in FY 2016 than in FY 2011. Some countries have notably increased their exports to the United States over the past five years, including China by 79 percent, Mexico by 61 percent, and Canada by 60 percent. Canada and France are the two largest exporters of cosmetics to the United States, and a significant volume is produced in other countries such as China, India, Mexico, Korea and Taiwan.

Approximately 29,000 foreign companies have been identified as the manufacturers or exporters of imported cosmetics in our import records, although few have voluntarily registered with FDA. FDA does not have authority to require registration for domestic or foreign cosmetic manufacturers, as it does for other commodities; as a result, the actual number of manufacturers may be different.

2. The number of imported products subject to inspections each year.

In FY 2016, of the 2.9 million lines of cosmetic products that arrived at U.S. ports, 9,871 received a physical examination by FDA inspectors, a rate well under one percent. We note that FDA conducts an electronic review of all imports via a risk-based screening tool and focuses inspection and sampling resources on those products with the potential for the greatest impact on public health.

3. The number of contaminated products intercepted each year.

FDA can refuse to allow entry of a product into this country if either electronic or physical examination suggests a potential violation of FDA requirements. Approximately 2,000 such cosmetic lines are refused each year, for reasons including labeling violations, the use of illegal color additives, and the appearance of contamination with filth or other contaminants. Countries with the ten highest refusal rates are China, India, Korea, Canada, France, Taiwan, Germany, the United Kingdom, Mexico, and Japan.

Of the 9,871 cosmetic imports physically examined by FDA in 2016, inspectors reported adverse findings with 1,474 of those imports, a rate of 15 percent. A number of those cosmetic imports were sampled and tested within FDA laboratories in 2016. Of the 364 subjected to laboratory testing, 73 resulted in adverse findings, a rate of 20 percent. The principal reasons for adverse

findings in laboratory tests were the presence of illegal color additives and microbial contamination. By a large margin, imports from China were identified with these concerns.

FDA currently has a number of Import Alerts involving specific cosmetic products or importers. Import alerts inform FDA field staff and the public that the Agency has enough evidence to allow for Detention Without Physical Examination (DWPE) of products that appear to be in violation of FDA laws and regulations. The principal reasons for issuing import alerts covering cosmetics have been illegal color additives, unsafe chemical substances, and microbial contamination.

The following current Import Alerts provide examples of the range of problems found with some cosmetic imports:

- Skin Whitening Creams (which FDA also classifies as drugs), labeled as cosmetics, that contain high levels of mercury;
- Eyeliners containing a product known as "Kohl," because of its heavy metal content;
- Anti-aging creams with structure-function and/or disease claims which make these products drugs. These products lack FDA approval as a drug and are unapproved new drugs;
- Cosmetic kits found with high levels of Citrobacter, Pseudomonas, and Staphylococcus bacteria;
- Eye makeup containing color additives, such as D&C Red #10 and D&C Red #7, that have been banned for decades as hazardous for eye exposure;
- Hairsprays that contain methylene chloride, an aerosol product that is a banned cosmetic ingredient under 21 CFR 700.19; and
- Temporary tattoo products that contain unapproved color additives and often falsely claim to be "FDA Approved."

Thank you for contacting us concerning this matter. If you have any further questions or concerns, please let us know.

Sincerely,

Anna K. Abram

Anna K. Abram
Deputy Commissioner for Policy, Planning,
Legislation and Analysis