U.S. FOOD & DRUG ADMINISTRATION

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

SEP 09 2019

Dear Representative Pallone:

Thank you for your letter of June 26, 2019 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 for an update on information you previously requested in a 2016 letter 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. As in our response to your 2016 letter on this matter, our response provides data on imported cosmetics.

We have compiled data on cosmetic imports for Fiscal Years 2017 and 2018, 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 are unable to provide Fiscal Year 2019 data as it is not yet available, but we will follow up with your staff once that data is available later this year.

We have restated your specific requests for information below in bold type, followed by our responses.

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

Table 1. Number of cosmetics imported each year for FY 2017 and FY 2018		
FISCAL YEAR	2017	2018
Total Cosmetic Lines [1, 2]	2,625,509	2,727,847

[1] These lines represent virtually every type of cosmetic marketed in this country, including lipsticks, eyeliners, nail polish, face powders, tattoo inks and more.

[2] When a shipment within FDA's jurisdiction is offered for entry into the United States, an entry notice must be filed with U.S. Customs and Border Protection, as well as, FDA. An entry notice may contain multiple types of products and each type of product (e.g., cartons of lipstick) must be declared as a separate line item in the entry notice. An "entry line" or "line item" refers to each portion of an entry that is listed as a separate item on an entry notice.

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There is no connection between the size (count of individual products per line or entry) of the shipment and the line or number of lines declared. For example, an entry line may contain 10 cartons of lipstick or 10,000 cartons of lipstick.

Table 2. Number of Countries Declared as the Origin of Cosmetics Imported in the U.S.		
FISCAL YEAR	2017	2018
Number of Countries[1]	181	177

[1] Some countries have notably increased their exports to the United States over the past five years, including China by 52 percent and Mexico by 61 percent. For 2017 and 2018, China, France, and Canada are the three largest exporters of cosmetics to the United States, and a significant volume is produced in other countries such as Korea, Mexico, Italy, Germany, and the United Kingdom.

Table 3. Number of Foreign Companies Identified as a Manufacturer or Exporter of Imported Cosmetics		
FISCAL YEAR	2017	2018
Number of Foreign Companies Identified as a Manufacturer or Exporter of Imported Cosmetics[1]	45,737	45,331

[1] 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.

Table 4. Number of Imported Cosmetic Products Subject to Inspections Each Year for FY 2017 and FY 2019		
FISCAL YEAR	2017	2018
Cosmetic Lines electronically screened[2]	All	All
Cosmetic Lines physically examined (unique count)	9,238	5,564
Cosmetic Lines sampled (unique count)[1]	384	245
Cosmetic Samples collected (total number)	433	289

[1] When an entry line is "sampled," one or more "samples" (products) are collected. Thus, the number of samples collected exceeds the number of lines sampled.

[2]FDA screens 100 percent of import entries electronically via our Agency automated screening tool, PREDICT, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting data system, which significantly improves FDA's risk-based targeting of imported products. A subset of those entries may be physically inspected and/or sampled, depending on the potential risk associated with them from this screening.

3. The number of contaminated products intercepted each year.

Table 5. Number of Cosmetic Import Refusals for FY 2017 and FY 2018		
FISCAL YEAR	2017	2018
Total Cosmetic Lines refused[1, 2]	1,192	973

[1] FDA can refuse to allow entry of a product into this country if either electronic or physical

examination suggests an appearance of a violation of FDA requirements. Cosmetic imports are refused for reasons including labeling violations, the use of illegal color additives, and the appearance of contamination with filth or other contaminants.

[2] For 2017 and 2018, countries with the ten highest refusal rates are: China, Russia, Korea, Mexico, India, Ivory Coast, Spain, Japan, United Kingdom, and the Philippines.

Table 6. Cosmetic Imports Sampled and Tested within FDA Laboratories		
FISCAL YEAR	**2017**	**2018**
Number of Samples Subjected to Lab Testing (unique count-analyzed)	420	283
Number Resulting in Adverse Findings (unique count-samples)	117	65
Rate of adverse findings[1,2]	27.8%	22.9%

[1] 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.

[2] FDA's PREDICT screening tool allows FDA to automate entry review and target higher-risk products, allowing expedited release of lower-risk products, especially those products and manufacturers with a good history of compliance. This allows FDA to focus its resources on higher-risk entries/products with physical inspection, sampling, and lab analysis. Therefore, the lines identified for examination or sampling would be expected to have higher rates of adverse findings based on FDA's use of the PREDICT screening tool. These rates should not be interpreted to be representative of all imported cosmetics.

As you noted regarding 2016 imports, FDA inspects only a small percentage of cosmetic imports. The cosmetics program at FDA is one of the smallest programs in the Agency. In FY 2018, cosmetics activities at the Office of Regulatory Affairs received $5.3 million dollars. These resources were used for conducting both domestic and imported cosmetic product fieldwork including activities such as sample collection, sample analysis, investigations, outbreak emergency response, and inspections for surveillance, emerging issues, and those targeted for follow-up.

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

Sincerely,

Karas Gross
Associate Commissioner for
Legislative Affairs