

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

June 26, 2019

The Honorable Ned Sharpless, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

As you are aware, I continue to be committed to ensuring the safety of cosmetic products. I outlined this commitment when I first released a bipartisan proposal to modernize cosmetic safety laws and strengthen the Food and Drug Administration's (FDA) authority to regulate cosmetic products in 2016, and I renewed this commitment when I released an updated discussion draft in March of this year. I last reached out to FDA in 2016 with the attached letter, which sought to gather information about the state of cosmetic imports. The information enclosed in FDA's response to this letter (also attached), was informative and deeply troubling.

Of particular concern is the fact that less than one percent of cosmetic products that arrived in U.S. ports in Fiscal Year (FY) 2016 were physically examined. And of those inspected, 15 percent had adverse findings such as containing illegal color additives, microbial contamination, and banned cosmetic ingredients. Given that FDA noted cosmetic imports have doubled over the last decade and that imports from China have gone up by 79 percent in the last five years, I find it troubling that FDA has not conducted any foreign cosmetic inspections in FY 2019 and intends to conduct no foreign cosmetic inspections in FY 2020.

I certainly recognize the need to provide FDA with additional authority and resources to expand the activities the agency is able to undertake in order to improve the safety of cosmetic and personal care products that are sold in the U.S. market. I also appreciate the steps FDA has taken, where possible, to address instances of consumer harm caused by cosmetics and personal care products. I especially appreciated FDA's work to alert consumers that the agency had detected asbestos in cosmetic products marketed to children and teens. In your announcement, you noted the need for FDA and Congress to work together to update the agency's outdated regulatory framework. As I said then, I commend your dedication to ensuring the safety of cosmetic products. I also agree that we need to work together to get unsafe cosmetics off the

The Honorable Ned Sharpless, M.D.

June 26, 2019

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market and ensure FDA is equipped to oversee an increasingly global cosmetic and personal care market.

As the demands of consumers grow and evolve, so must the efforts of Congress to protect them. It is in this spirit that I ask that FDA update the Committee on the foreign inspections information I requested in my December 20, 2016 letter to reflect data for FY 2017-2019. To reiterate, this includes providing the Committee staff with answers regarding the following:

1. The number and kinds of personal care products imported each year;
2. The number of imported products subject to inspections each year; and,
3. The number of contaminated products intercepted each year.

In addition, I would also appreciate it if you would provide Committee staff with any other materials or information that might inform the development of cosmetics legislation.

I would appreciate your response to this inquiry as soon as possible, but no later than July 8, 2019. If you have any questions regarding this request, please contact Kimberlee Trzeciak or Megan Howard of the Democratic staff at 202-225-2927.

Sincerely,

A handwritten signature in blue ink, appearing to read "Frank Pallone, Jr.", with a stylized flourish at the end.

Frank Pallone, Jr.
Chairman

Attachments

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

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December 20, 2016

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

As you know, I have a longstanding commitment to cosmetics safety. In September 2016 I released a bipartisan proposal to strengthen the Food and Drug Administration's (FDA) authority to regulate cosmetic products. I am hard at work refining this proposal and hope to introduce legislation next year that will modernize cosmetic safety laws and help ensure that the cosmetics products Americans use each day are safe.

Among other things, this legislation would give FDA the authority to require any manufacturer, processor, packer, or holder of a cosmetic product to register with the Agency. The legislation also would give FDA the authority to collect data and information on cosmetic ingredients and require FDA to review such ingredients to determine if they are safe for use in cosmetics. Additionally, the legislation would help ensure that all cosmetic manufacturers comply with good manufacturing practices established by FDA.

To inform this legislative effort, I am requesting additional information about cosmetic imports. As you know, cosmetics are imported from many countries but most are not inspected or sampled upon entry into the U.S. Although cosmetic products produced abroad are required to meet the same regulatory requirements as cosmetics produced domestically, FDA does not determine the extent to which companies are substantiating the safety of these imported products. I understand that cosmetic imports are on the rise in the United States and that there have been a number of adverse events associated with imported cosmetics. For example, in recent years FDA warned consumers of the dangers of mercury in imported skin-lightening and anti-aging products. Exposure to mercury can have serious adverse health consequences. Skin creams containing mercury are usually manufactured overseas and sold illegally in the United States, often in stores that market to Latino, Asian, African, or Middle Eastern communities. Given this, I am concerned about the short and long-term risks that imported cosmetics may pose to consumers and their families.

I want to better understand the cosmetics import industry to ensure the legislation I will introduce sets out a modern cosmetics regulatory framework that gives FDA the tools, information, and resources necessary to protect Americans from all potentially dangerous cosmetics products. As such, I request that you provide answers to the Committee staff regarding the following:

1. The number and kinds of personal care products imported each year;
2. The number of imported products subject to inspections each year; and,
3. The number of contaminated products intercepted each year.

In addition, please provide Committee staff with any other materials or information that might inform the development of cosmetics legislation.

I would appreciate your response to this inquiry as soon as possible, but no later than December 30, 2016. If you have any questions regarding this request, please contact Megan Velez of the Democratic staff at 202-225-3641.

Sincerely,

A handwritten signature in blue ink that reads "Frank Pallone, Jr." with a stylized flourish at the end.

Frank Pallone, Jr.
Ranking Member



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 lines¹ 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,

A handwritten signature in black ink, appearing to read "Anna K. Abram", with a stylized flourish at the end.

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