



CONSUMER
HEALTHCARE
PRODUCTS
ASSOCIATION

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Submitted electronically

December 23, 2020

Bureau of Industry and Security, Office of Technology
and Security
U.S. Department of Commerce
Washington, DC

Re: Docket No. BIS-2020-0034
Comments on Condition of the Public Health Industrial Base and
Recommend Policies and Actions to Strengthen the Public Health
Industrial Base to Ensure Essential Medicines, Medical
Countermeasures, and Critical Inputs Are Made in the United States
AGENCY: Bureau of Industry and Security
ACTION: Notice of request for public comments
85 Fed. Reg. 77428 (December 2, 2020)

Dear Sir or Madam:

The Consumer Healthcare Products Association (CHPA) appreciates the opportunity to comment on the above captioned request for comments on the condition of the public health industrial based and recommendations to strengthen it. CHPA, founded in 1881, is the national trade association representing leading manufacturers and marketers of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices (Class I and certain Class II devices available directly to consumers without professional intervention). CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products. The ingredients in a number of CHPA member company products are considered essential medicines, and CHPA member products help Americans get and stay well for a range of common conditions. As such, we have an interest in this request for comments.

Our comments address general themes raised by the 17 areas of specific questions in the request for comments.

Supply chain resilience. Supply chain resilience is essential to provide Americans with quality, safe, beneficial consumer healthcare products. Resilience in turn depends on a diverse, global supply chain which reduces the risk of shortages or disruptions that may occur in a particular geographical

area. Disruptions can include not only a pandemic or a geopolitical issue, but issues *within* the United States, such as a highly localized disease outbreak or a natural disaster. Having ingredient suppliers in different parts of the world allows manufacturers an alternate source of ingredients for procurement when an interruption occurs in one location to avoid larger disruptions.

Domestic finished product manufacturing capacity. For OTC medicines, manufacturing is highly globalized, including a significant U.S. capacity. Based on a 2017 CHPA review of FDA information, there are at least 1,000 OTC manufacturing facilities in the U.S.

Ingredient capacity. The ingredients within our members' products are even more diverse. Some key ingredients are only available from suppliers outside of the U.S. One example of this can be naturally-derived ingredients, where either growing conditions or the OTC medicine proportion of a larger and different crop market means there is simply no U.S. sourcing available. Another example is active pharmaceutical ingredients (APIs), where much of the manufacturing of APIs found in finished OTC products has gradually moved out of the U.S. FDA estimated that as of August 2019, 72 percent of the API manufacturers supplying the U.S. market were overseas (~13 percent are in China). Manufacturing APIs overseas is often cheaper, resulting in lower costs for the medicines purchased and used in the United States. As noted above, CHPA supports a globally diverse supply chain, which includes increased manufacturing in and throughout the United States and its territories.

The fact that the U.S. has not experienced major OTC medicine shortages during the COVID-19 pandemic is illustrative of the strength of this diverse supply chain. For example, glycerol is a component of hand sanitizers that help fight the novel coronavirus and producers of these products have faced challenges getting the raw materials they need to make these items. Globally, companies were beginning to see limitations on the amount of glycerol that could be purchased from their typical suppliers. Manufacturers still needed glycerol for OTC hand sanitizers or other medicines and were able to source the material from other suppliers with minor interruptions of supply.

Fostering greater U.S. capacity. While CHPA is not currently advocating for specific measures to increase U.S. manufacturing capacity, we are open to engaging with the Commerce Department and other stakeholders on a number of ideas presented in the request for comments. For instance, for a number of decades, tax incentives were provided for manufacturing in Puerto Rico, which have since expired. Multilateral cooperation among allies to assure a manufacturing base among allied countries would be another example that could be discussed. Finally, when facilities are constructed in

the U.S., we appreciate coordination with FDA on efficient regulatory reviews and site inspections.

Conclusion. Supply chain resilience is essential to assure consumer healthcare products Americans depend on remain widely available, including in times of disease outbreaks or global crises. While there is a strong U.S. manufacturing capacity for consumer healthcare products in finished dosage form, supply chain resilience relies on a diverse, global supply chain to reduce the risk of shortages or disruptions that may occur in a particular geographical area. Such disruptions not only include pandemics or geopolitical issues, but issues *within* the U.S., such as a natural disaster. Having ingredient suppliers in different parts of the world allows manufacturers an alternate source of for procurement when an interruption occurs to reduce the impact of such disruptions.

Thank you for the opportunity to submit these comments.

Respectfully submitted,

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