CHPA® | CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

Taking healthcare personally.

Submitted via www.regulations.gov

November 28, 2024

U.S. Department of Justice
National Security Division
Foreign Investment Review Section
175 N Street NE, 12th Floor
Washington, DC 20002

Re: Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons; 89 *Fed. Reg*. 86116-86227, Docket No. NSD 104

Dear Sir or Madam:

The Consumer Healthcare Products Association ("CHPA") submits these comments on the Proposed Rule entitled "Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons" published on October 29, 2024 ("Proposed Rule")[1] to implement Executive Order 14117 "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern" (the "EO").

CHPA, founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter ("OTC") medicines, dietary supplements, and OTC medical devices. For more than 143 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. CHPA members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.[2]

CHPA supports well-tailored efforts to protect the sensitive personal data of U.S. persons, including efforts intended to protect and strengthen the national security of the United States. Through the inclusion of the proposed exemptions in sections 202.510 and 202.511, the Proposed Rule strikes a better balance than the Advance

[1] DOJ, Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons; Availability, 89 *Fed. Reg*. 86116-86227 (Oct. 29, 2024). Accessed from https://www.govinfo.gov/content/pkg/FR-2024-10-29/pdf/2024-24582.pdf on November 27, 2024.

[2] CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy. Visit www.chpa.org.

Notice of Proposed Rulemaking[3] to implement the EO in a way that protects national security interests while taking steps to not unduly interfere with the development and delivery of therapies to patients. CHPA encourages the Department of Justice ("DOJ") to adopt these proposed exemptions in the final rule, and to make them permanent features of the proposed data access framework.

Certain aspects of the proposed exemptions in sections 202.510 and 202.511, however, are too narrow and too ambiguous as drafted. The final rule to implement the EO should incorporate the following changes to better achieve a balance between protecting national security interests and protecting patients' access to essential, everyday medical products and dietary supplements.

1. Expand the scope of covered products under the exemptions to include dietary supplements.

CHPA supports DOJ's proposal to include exemptions for covered product authorizations, as well as clinical investigations and post-marketing surveillance data, for drugs and medical devices. In many markets, OTC drugs and medical devices—like their prescription counterparts—are subject to data submission requirements that allow them to be sold directly to consumers. For example, China's National Medical Products Administration ("NMPA") requires that medical device applicants submit a clinical trial database, including individual coded patient records, when submitting foreign data as part of their clinical evaluation in a registration application for pre-market approval.[4] Similarly, these products are subject to postmarketing adverse event reporting requirements. The proposed exemptions in sections 202.510 and 202.511, therefore, are necessary to ensure that OTC drugs and medical devices can enter and stay on the market, and that patients around the world can access these needed medical products.

CHPA strongly recommends that DOJ expand the proposed exemptions to apply to dietary supplements, which are also known as "health foods" in certain markets. Like drugs and devices, these products may be subject to pre-market approval requirements, such as in China where they are required to submit a pre-market filing or registration, depending on the ingredients and claims of the health food. There are two types of health foods in China: (1) those that make claims of supplementing vitamins and minerals, and (2) those that make one of twenty-four permitted functional claims, *e.g.*, strengthening immunity, improving sleep, relieving physical

[3] DOJ, Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern, 89 *Fed. Reg.* 15780 (Mar. 5, 2024).

[4] NMPA, Guidelines for Registration Review of Medical Device Clinical Trial Data Submission Requirements (2021), https://www.cmde.org.cn/flfg/zdyz/fbg/fbgqt/20211126085606616.html (accessed on November 28, 2024). We note that OTC products can require pre-market approval (as they do in China), and certain drugs and devices that are considered OTC in the United States may be considered prescription medical products in other jurisdictions, and subject to further pre-market approval requirements.

fatigue. Applications for pre-market approval of functional claim health foods require data to support their safety and effectiveness. Depending on the claim, these data can come from laboratory testing, animal testing, and human testing (*i.e.*, data from "human food studies"). For example, human data is required for claims like "helps maintain healthy blood lipids levels," "improves anti-oxidants," and "helps improve memory."[5] Although data to support these claims should generally be from subjects in China, authorities will accept and rely on overseas data to support health food registration applications, and such data can be helpful in ensuring that the product is ultimately approved.

Dietary supplements are an important part of improving or maintaining health for many people. Given their significance in promoting public health, and the fact that they can be subject to similar regulatory data submission requirements as drugs and medical devices,[6] CHPA urges DOJ to expand the scope of the proposed exemptions to include dietary supplements (health foods).

2. Expand the scope of the proposed exemption in section 202.510 to include restricted employment and vendor agreements.

DOJ should expand the scope of the proposed exemption in 202.510 to include transactions with affiliates and subsidiaries of a U.S. company in a country of concern and vendors that are covered persons under the Proposed Rule to store, analyze, prepare, and submit data to regulators that are necessary to obtain or maintain research or marketing authorizations.

Local agents must be involved in submissions to regulators when a medical product marketing authorization holder ("MAH") or applicant does not reside or have a place of business within the country where the application is being submitted, even in the United States.[7] This is true in countries of concern, like China, where a local agent must submit regulatory approval applications to the State Administration for Market Regulation as well as other regulatory filings for overseas MAHs and applicants for

[5] Claims requiring human data are set forth in the Health Food Functional Testing and Evaluation Methods (2023 Ed.).

[6] Relatedly, CHPA supports DOJ's position that the exemption in proposed section 202.510 applies even where U.S. Food and Drug Administration ("FDA") authorization has not been sought or obtained, and that seeking authorization to market in the United States before seeking regulatory approval from a country of concern is not necessary. 89 Fed. Reg. at 86137. This approach is particularly relevant to dietary supplements, which are not required to obtain U.S. FDA approval before they are marketed and, in many cases, can be introduced to the U.S. market without notifying U.S. FDA.

[7] See 21 C.F.R. §§ 312.23(a)(1)(ix) & 314.50(a)(5).

drugs,[8] devices,[9] and dietary supplements.[10] These agents are often affiliates or subsidiaries of overseas applicants or unrelated third-party vendors or development partners that have internal regulatory and quality personnel, who assist with compilation, translation, and formatting of application materials prior to submission, including clinical data. Their personnel have years of experience that are indispensable to registration application preparation, submission, and maintenance. It is important, therefore, that these essential actors be allowed access to bulk U.S. sensitive personal data under employment agreements and/or vendor agreements in order to store, analyze, prepare, or submit an application or other filing to regulators in a country of concern in order to obtain or maintain regulatory authorization to research or market a covered product.

3. Clarify the meaning of "de-identified" under the exemptions.

Both proposed exemptions use the term "de-identified" to limit the scope of the exemption, but the term is undefined in both proposed section 202.510 and section 202.511. Consistent with DOJ's position in the preamble to the Proposed Rule,[11] CHPA recommends that DOJ explicitly adopt a definition of de-identified that is consistent with the privacy protection standards required by the U.S. Food and Drug Administration ("FDA") as part of post-marketing adverse event reporting—*i.e.*, that the data be coded and not include individual names or addresses.[12] This approach, which should apply to clinical trial data as well as adverse event reporting data, is consistent with industry standards and best practice. DOJ should explicitly define the standards for de-identification consistent with this approach in the final rule.

4. Address other ambiguities in the proposed exemption in section 202.510.

CHPA encourages DOJ to clarify other ambiguous aspects of the proposed exemption in section 202.510. First, DOJ should clarify that "regulatory authority" means any

---

[8] Measures for the Administration of Drug Registration, Art. 9 (2020) (requiring overseas drug MAHs to designate a Chinese entity to be responsible for drug registration); NMPA, Interim Provisions on the Administration of the Designation of Domestic Responsible Persons by Overseas Drug Marketing Authorization Holders (No. 137) (Nov. 14, 2024) (requiring local agents to perform, among other things, postmarketing reporting and registration changes).

[9] Medical Device Supervision and Administration Regulation, Articles 15-16, 20 (2021) (requiring overseas medical device applicants to appoint an agent entity in China to assist with communications and submissions to the Center for Medical Device Evaluation, an affiliate of NMPA); Medical Device Adverse Event Monitoring and Re-Evaluation Measures, Article 27 (2018) (requiring overseas medical device applicants to submit reports, through their local agents, of adverse events that occur overseas if related to a device that is registered and sold in China and caused or could have caused serious injury or death).

[10] Administrative Measures on Health Food Registration and Filing, Articles 11-13 (2016) (requiring overseas health food applicants to appoint local entities in China to act as their agents for purposes of registration and filing applications).

[11] *See* 89 *Fed. Reg.* at 86139.

[12] *See* 21 C.F.R. § 314.80(i).

regulator, at any level of government, that is involved in reviewing and/or granting authorizations necessary to research or market a covered product in the country of concern. Second, DOJ should provide additional guidance about what data would not be considered "reasonably necessary" to analyze a covered product's safety or efficacy. As part of that guidance, CHPA encourages DOJ to adopt a flexible approach, as what is necessary can differ depending on the product at issue. Indeed, what is "reasonably necessary" could vary across different covered product types, *e.g.*, medical device versus drug product, as well as within a particular type of covered product, *e.g.*, medical devices—which could range from dental floss to OTC hearing aids that use geolocation data to automatically adjust listening settings to different locations (*e.g.*, at a concert versus a library) to complex surgical assistance equipment.

5. Adopt a delayed implementation date to allow companies adequate time to come into compliance with the data access framework.

DOJ should adopt a delayed implementation date for the final rule implementing the EO of at least one year from issuance of the final rule. There are a number of aspects of the Proposed Rule that remain unsettled—including the scope of the proposed exemptions in section 202.510 and 202.511—and manufacturers of consumer healthcare products (among other stakeholders) will need time to review the final rule and then bring their data flow, and the policies and systems that govern that flow, into compliance with the final rule.

* * *

CHPA appreciates the opportunity to provide comments to DOJ on the Proposed Rule. Please do not hesitate to contact us if you have any questions about our suggestions.

Respectfully Submitted,

Marcia D. Howard, Ph.D., CAE

Digitally signed by Marcia D. Howard, Ph.D., CAE
Date: 2024.11.28 01:14:27 -05'00'

Marcia D. Howard, Ph.D., CAE
Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association
Email: mhoward@chpa.org
Phone: 202 429 3532 (office)

CC: Lee Licata, Deputy Chief for National Security Data Risks, Foreign Investment Review Section, National Security Division (sent via email to NSD.FIRS.datasecurity@usdoj.gov)