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VIA ONLINE SUBMISSION

September 10, 2026

Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services

Kyle Diamantas
Acting Commissioner
Food and Drug Administration (FDA)

RE: Comments on the Proposed Rule, "Drug Establishment Registration and Drug Listing Requirements for Establishments Engaged in Distributed Manufacturing and Certain Foreign Establishments." **[Docket No. FDA-2025-N-6075; RIN 0910-AI94; 91 FR 42888].**

Secretary Kennedy and Acting Commissioner Diamantas:

This public comment is submitted on behalf of the America First Policy Institute ("AFPI"). AFPI is a 501(c)(3) non-profit, non-partisan research institute dedicated to advancing policies that put the American people first. Its guiding principles are liberty, free enterprise, the rule of law, an America-first foreign policy, and the belief that American workers, families, and communities are key to our country's success.

America's pharmaceutical supply chain remains largely dependent on foreign manufacturing in a small number of countries, such as China and India, for the key starting materials (KSMs) and active pharmaceutical ingredients (APIs) that make up the generic drugs American patients take every day. This proposed rule provides the Food and Drug Administration (FDA) with visibility into foreign establishments that manufacture drug components for drugs in the American market and removes a regulatory barrier to manufacturing technologies that can bring drug production back to American soil.

We appreciate the opportunity to comment on the Agency's proposed rule, "Drug Establishment Registration and Drug Listing Requirements for Establishments Engaged in Distributed Manufacturing and Certain Foreign Establishments."

Legal Authority for Proposed Rule
Section 510(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(i)) requires every person engaged in the manufacturing, preparation, propagation, compounding, or processing of a drug to register their establishment, and section 2511 of the Preparing for and Responding to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act) amended section 510(i) to require registration of foreign establishments whose drugs are imported or offered for import into the United States, regardless of whether those drugs undergo further processing at another foreign establishment before importation. The proposed amendments to §§ 207.17 and 207.41 conform to the Agency's regulations to the statute as amended, eliminating any perceived inconsistency that noncompliant foreign establishments might otherwise exploit. Similarly, the proposed distribution manufacturing provisions rest on the Agency's registration authorities under section 510 and its general rulemaking authority under section 701(a) of the FD&C Act (21 U.S.C. 371(a)).

Foreign Establishment Registration and Drug Listing
AFPI strongly supports the proposed amendments to §§ 207.17(a)(2) and 207.41(d). For too long, foreign API manufacturers have avoided registration and listing simply because they distribute their products to other foreign establishments rather than shipping directly to the United States, even when finished drugs from those APIs end up in American pharmacies and American homes. This creates a blind spot at a vulnerable point in the supply chain. An unregistered foreign API plant goes uninspected, and registration of these establishments is the "primary source" for FDA's site-selection model for surveillance inspections.

Distributed Manufacturing Establishment Registration
AFPI also supports the proposed registration pathway for distributed manufacturing establishments (DMEs). Under the current rules, a hub and every one of its distributed manufacturing units (DMUs) must register separately. This penalizes the very manufacturing model that the domestic drug supply needs: distributed production that can add or remove production units as demand changes and can relocate in an emergency. A single, streamlined registration would allow the FDA to maintain oversight while removing a barrier to onshoring.

We encourage the Agency to vigorously enforce the finalized rule and prioritize newly registered foreign API establishments in its risk-based inspection planning, particularly in countries where FDA has historically had a limited footprint or has been denied access to conduct full inspections[1].

Downstream KSM Suppliers Should Be Documented by API Registrants
The steps taken in the proposed rule make significant progress toward documenting supply chain dependencies for American pharmaceuticals. However, the proposed changes to §§ 207.17 and 207.41 regarding foreign establishment registration, as they would be enforced under existing CGMP practices and inspections, present a practical opportunity that should be emphasized and realized in enforcing the rule: clarifying and retaining documents for inspection related to the purchase of key starting material (KSM) supplies provided to API registrants under the rule.

KSM suppliers themselves are not subject to inspection under this regulation, nor would it be statutorily appropriate to require their registration under the proposed scheme. However, for the FDA's purposes of understanding the scope of foreign supply of these products as well as the safety of such products, it would be appropriate for the registrants themselves to make available—through existing documentation such as purchase orders, bills of lading, etc.—to the FDA the country of origin for KSMs as they are purchased for further manufacture or processing.

As outlined in ICH Q7, "Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients," records, including those of "raw materials [and] intermediates," should include "the name of the manufacturer, identity, and quantity of each shipment of each batch"[2] as part of CGMP. Further, the "supplier; the supplier's control number(s), if known, or other identification number" should also be included. In essence, ICH Q7 seeks to document (primarily for consumer safety purposes) the

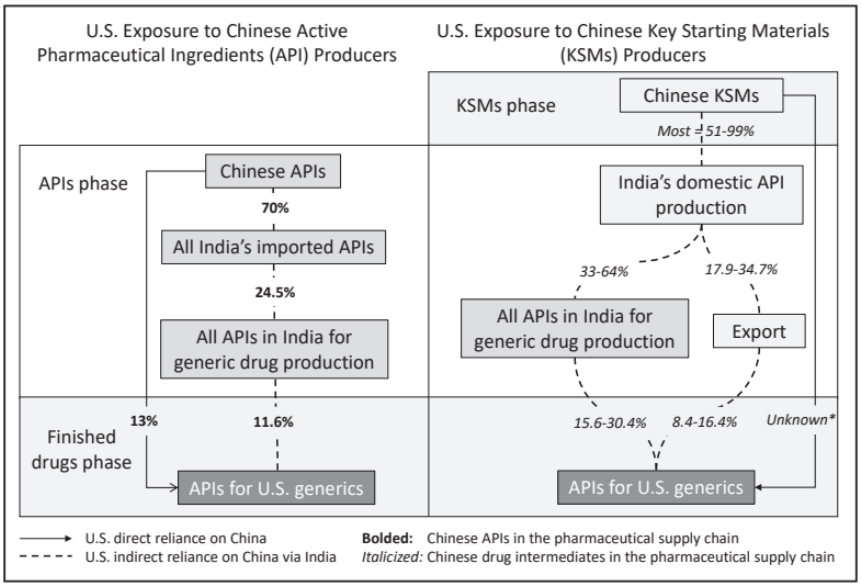
[1] Particularly the People's Republic of China, as evidenced by several instances, including https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/xiamen-kang-zhongyuan-biotechnology-co-ltd-719320-03232026, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tianjin-darentang-jingwanhong-pharmaceutical-co-ltd-683619-10302024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-bangli-medical-products-co-ltd-510524-01262017, and https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/shandong-analysis-and-test-center-524254-06222017. This comes in addition to several previous consumer health concerns due to processing of products in the PRC, such as the 2008 Heparin and 2018 valsartan recalls, both of which occurred due to improper manufacturing as a cost-cutting measure in the PRC.
[2] Food and Drug Administration (2016, September). *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients: Guidance for Industry.* Department of Health and Human Services. https://www.fda.gov/media/71518/download. Quote at page 16.

manufacturer of the raw materials and, through this effort, the country of origin as a matter of course. This information should simultaneously be used for consumer safety to mitigate supply risks by documenting and understanding supplier concentration at the KSM stage.

Critically, API manufacturers—particularly those that market themselves as independent of foreign adversary suppliers subject to significant supply chain risk—likely rely heavily on those same adversaries for KSMs.[3] As emphasized by the United States-China Economic and Security Review Commission (USCC), "[the Department of War] designated [27% of 211 pharmaceuticals on the Essential Medicines and Medical Countermeasure list] as very high risk, including 5% of essential drugs made with an API sourced from China and 22% sourced from *an unknown country"* [emphasis added].[4] This creates a supply chain risk because of the unknown origin of these products, as well as risks posed by the known suppliers.

Various estimates have been made to understand this vulnerability, reaching varying conclusions, none of which are reassuring. Because requirements under previous regulatory regimes were lackluster, estimates of how many APIs—particularly generics—vary widely. The USCC estimates that up to 50% of the People's Republic of China's KSMs enter APIs for American-bound pharmaceuticals via "unknown" channels that may pass through the Republic of India.[5] This lack of visibility creates vulnerabilities at several distinct levels that the FDA can address through documentation already standard under ICH Q7 and general CGMP for API and finished-product documentation, which would apply to registrants under the rule.

Figure 1
USCC Diagram of Pharmaceutical Supply from the People's Republic of China



Any single-country-of-origin concentration of this severity should be cause for alarm; reliance on the PRC presents unique challenges due to obfuscation and lack of clarity in the PRC's economy. Verification of the USCC's estimate of the "unknown" ~50% origin would be a considerable step forward in pharmaceutical supply chain transparency. The PRC has deliberately, through extensive industrial policy[6],

[3] As outlined at 15 CFR § 791.4.
[4] https://www.uscc.gov/sites/default/files/2025-11/Chapter_9--Chained_to_China_Beijings_Weaponization_of_Supply_Chains.pdf, particularly that PRC scholars with publications in Xinhua, a state media service, have "publicly suggested using China's control of APIs to retaliate against the United States." Two of these Xinhua publications are linked in footnote 7.
[5] https://www.uscc.gov/sites/default/files/2025-11/Chapter_9--Chained_to_China_Beijings_Weaponization_of_Supply_Chains.pdf, page 492, with the USCC noting separately that "poor data visibility" between India and the PRC makes it "difficult to determine the exact proportion[s]." It is our belief that any proper documentation of this problem requires inspection of documents in *both* India and the PRC for data consistency.
[6] https://www.uscc.gov/sites/default/files/2025-06/Stephen_Schondelmeyer_Testimony.pdf, noting that the PRC has strategically targeted the pharmaceutical industry via "industrial policy that prioritized pharmaceutical production of [KSMs and APIs] due to China's strategic economic investments, regulatory flexibility, lower labor costs, economy of scale production, subsidized

created a concentration of pharmaceutical upstream supply that poses risks—such as the possible intentional withholding[7] of pharmaceuticals or disruption as part of a larger geopolitical conflict—that must be documented and understood to mitigate risks to the American people.

Additional inspections in facilities that comprise a state-coordinated effort to centralize global pharmaceutical manufacturing would be highly useful for understanding, countering, and mitigating the risks associated with such concentration. Without this information, risks only grow more severe.

Thank you for your consideration,

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manufacturing infrastructure, global trade practices, and other products." This is related to the production of fentanyl precursors in the PRC, which is sustained by subsidies and industrial policy in a very similar fashion.

[7]Entertained on Xinhua, the PRC's state news agency's website, with examples such as https://www.xinhuanet.com/politics/2019lh/2019-03/09/c_137872771.htm and https://www.xinhuanet.com/politics/2020-03/04/c_1125660473.htm, which include excerpts such as "[i]f we were to reduce exports [of antibiotics], the medical systems of certain developed countries would cease to function properly," and "[i]f China were to retaliate at this moment […] by placing strategic controls on medical products and banning exports to the United States—the United States would be plunged into an ocean of the novel coronavirus."