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Commerce's Section 232 Pharmaceutical Investigation: Opportunities for Companies Able to Comment by the May 7, 2025 Deadline

Client Advisories

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April 17, 2025 – On April 1, Secretary of Commerce Howard Lutnick initiated an investigation "to determine the effects on the national security" of the United States "of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products." This includes "both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items." ¹ On April 14, the Department of Commerce announced this investigation and invited public comment within 21 days of the investigation's official notification in the Federal Register ² on April 16, 2025, i.e., by May 7, 2025.

Although we expect some form of tariffs or other measures to result from this investigation under Section 232 of the Trade Expansion Act of 1962, the outcome is not a foregone conclusion for companies located in countries that are traditionally aligned with U.S. national security interests and who can demonstrate that they play a key role in promoting those interests. There is historical precedent, for example, for a Section 232 investigation to conclude that national security concerns do not justify the imposition of tariffs or other measures as to non-U.S. activity in countries whose governments are aligned with the U.S. and that are geographically situated such that, for example, various conflict scenarios would not threaten supply. $\underline{3}$

Accordingly, companies who believe they have a strong case for avoiding or significantly mitigating the impact of eventual Section 232 tariffs on U.S. imports of pharmaceuticals and pharmaceutical ingredients, and derivative products should consider acting quickly to participate in the public comment window that is open only until May 7, 2025.

Given Secretary Lutnick's statements during his confirmation process about using tariffs to backstop export controls and the administration's announcement of innovative "secondary tariffs" to punish countries that continue to do business with sanctioned countries, companies participating in the public comment process should also consider highlighting current or potential enhancements to their economic sanctions and export controls compliance programs to mitigate the risk of smuggling or evasion that would jeopardize U.S. national security interests.

Contact Hughes Hubbard & Reed's Sanctions, Export Controls and Anti-Money Laundering practice group to learn how we can help you to evaluate what potential opportunities the public comment period presents.

- Dep't of Comm., <u>Notice of Request for Public Comments on Section 232 National Security Investigation of Imports</u> of Pharmaceuticals and Pharmaceutical Ingredients, BIS-2025-0022 (released Apr. 14, 2025; published on Apr. 16, 2025). <u>e</u>
- 2. <u>90 Fed. Reg. 15,951</u> (Apr. 16, 2026). <u></u>
- 3. This was the conclusion of the 1983 Section 232 investigation—initiated by the Secretary of Defense—into "<u>The</u> <u>Effect of Imports of Nuts, Bolts, and Large Screws on the National Security</u>." ←

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