232-Pharmaceuticals Declaration

Save Reset Form

Complete this form if you have products flagged as pharmaceuticals subject to 232 duties per 91 FR 18183 and CSMS #69395344. If you need more space, please attach a list of goods to this form and indicate all elements of the table below. Failure to pay duties on subject goods can result in adverse action from CBP. By signing this form, you acknowledge that you have read the entire form and understand your responsibilities as the importer of record.

Part #/Product ID	Description	HTSUS	Country of Origin	99 Number to Declare

Complete for Single Shipment Declarations ONLY

Shipment Entry No., Invoice or Reference No.: _____

Complete ONLY for Blanket Declarations

Annual Certificate Period, covering from _____ to _____

I hereby certify that the previous statements regarding my products are true and correct to the best of my knowledge.

Company Name: _____ Account #: _____

Name of Certifying Individual: _____ Title: _____

Phone No.: _____ Email: _____

Signature: _____ Date: _____

Further Guidance

Effective July 31, 2026 for some companies, Section 232 duties are due on certain patented pharmaceuticals per 91 FR 18183 (Annexes for easier searching, (c) are the subject HTSUS numbers). Further guidance can be found in CSMS #69395344. For companies not identified by the secretary of commerce, Section 232 duties on certain pharmaceutical articles are effective September 29, 2026. For purposes of these duties, the following definitions apply:

"Pharmaceutical articles" refers to imported articles classifiable in the provisions enumerated in this subdivision that are pharmaceutical products or that are ingredients (active pharmaceutical ingredients and key starting materials) classifiable in the provisions enumerated in this subdivision used to make pharmaceutical products.

"Patented pharmaceutical articles" are pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") or in the FDA's Lists of Licensed Biological Products ("Purple Book"); and ingredients (active pharmaceutical ingredients and key starting materials) for such articles.

"Generic pharmaceutical articles" are FDA-approved pharmaceutical articles, and associated ingredients, that are not subject to a valid, unexpired U.S. patent and are off exclusivity. A generic pharmaceutical article is an active pharmaceutical ingredient or any component in a finished dosage form product that is used in a drug product or biosimilar biological product approved pursuant to a qualifying application; or a drug product or biosimilar biological product approved or licensed pursuant to a qualifying application. A qualifying application is: (a) an abbreviated new drug application submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"); (b) a new drug application submitted under section 505(b)(2) of the FDCA that has been requested to be or that has been deemed therapeutically equivalent to a listed drug; (c) a biosimilar biologics application submitted under section 351(k) of the Public Health Services Act; or (d) an application for an authorized generic drug or authorized biological product, as those terms are described in section 505(t) of the FDCA and 42 U.S.C. § 1320f1(e)(2)(B)(ii), provided that the products are imported by a generic or biosimilar manufacturer.

Chapter 99 Numbers for Section 232 Pharmaceuticals:

9903.04.60 – Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) that are not imported for companies identified by the Secretary and imported on or after 9/29/26. Rate of duty is 100%

9903.04.61 – Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) imported for companies identified by the Secretary and imported on or before 9/28/26. Rate of 232 duty is 0%. **Regardless of company, effective July 31, 2026, all importers of goods classified under the subject Chapter 29 and 30 HTSUS classifications are required to report an applicable Chapter 99 HTSUS classification. For imports from all other companies, no Section 232 duties are due on imports of patented pharmaceuticals and ingredients until September 29, 2026. From July 31, 2026, through September 28, 2026, importers of patented pharmaceuticals and ingredients from all other companies should file the zero duty HTSUS 9903.04.61. The companies subject to Section 232 duties on patented pharmaceuticals and ingredients as of July 30, 2026, are listed in Annex III of the Proclamation.**

9903.04.62 – Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) that are the product of Japan, an EU country, South Korea, Switzerland, or Liechtenstein. Rate of duty is 15%.

9903.04.63 – Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) that are the product of the United Kingdom. Rate of 232 duty is 0% per CSMS #69415934.

9903.04.64 - Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) imported for companies subject to an onshoring plan approved by the Secretary of Commerce. Rate of 232 duty is 20%. Based on a notification from the Commerce Department, there are no companies with a qualifying onshoring plan currently eligible for the duty rate under 9903.04.64.

9903.04.65 - Patented pharmaceutical articles classifiable in any HTSUS listed in U.S. Note 40(c) that meet the requirements under 9903.04.64 AND are imported for companies that have entered into a Most-Favored-Nation pharmaceutical pricing agreement with the Secretary of Health and Human Services. Rate of 232 duty is 0%.

9903.04.66 – Drugs and associated ingredients classifiable in any HTSUS listed in U.S. Note 40(c) for all approved indications that are designated as orphan pursuant to the Orphan Drug Act and its implementing regulations; nuclear medicines; plasma derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological and nuclear threats; or other specialty pharmaceutical products identified by the Secretary of Commerce or pharmaceutical products for animal health imported from a jurisdiction that has a current or forthcoming trade and security framework or that meet an urgent U.S. health need. The Secretary shall publish a Federal Register notice when the conditions above are met and shall notify CBP of all such products. Rate of 232 duty is 0%.

9903.04.67 – Generic pharmaceutical articles as defined above. 232 duty does not apply.

9903.04.68 – Pharmaceutical products with an active pharmaceutical ingredient packaged in dosage form that is a product of the United States. 232 duty does not apply.

9903.04.69 – Articles that are classifiable under any HTSUS listed in U.S. Note 40(c) that are not pharmaceutical articles as defined above. 232 duty does not apply.