American Association of Exporters & Importers

The Honorable Jeffery Kessler
Undersecretary of Industry and Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Avenue NW
Washington, DC 20230

August 24, 2026

Re: Request for Clarification -- Proclamation 11020, "Adjusting Imports of Pharmaceuticals and Pharmaceutical Ingredients into the United States" (April 2, 2026), and Related CBP Guidance (CSMS #69395344)

Dear Undersecretary Kessler:

On behalf of the American Association of Exporters and Importers (AAEI), we write to share unresolved certain definitions and provisions in Proclamation 11020 and its Annex I (the "Proclamation"), and to identify several inconsistencies between the Proclamation, Annex I, and U.S. Customs and Border Protection's implementing guidance in CSMS #69395344 (the "CSMS Guidance").

AAEI members—U.S. importers, exporters, and trade service providers—are directly responsible for managing the day-to-day execution of U.S. trade. AAEI respectfully submits this letter on behalf of its member companies -- importers and exporters of finished pharmaceutical products, active pharmaceutical ingredients, and key starting materials across the branded, generic, biosimilar, and specialty pharmaceutical sectors. Our members collectively classify and declare a substantial volume of imports under new HTSUS headings 9903.04.60-9903.04.69, effective July 31, 2026, for Annex III companies and September 29, 2026, for all other companies. Ambiguity in the underlying definitions creates a real risk of inconsistent treatment across importers, misclassification, and potential retroactive liability industry wide. We respectfully request the Department's guidance on the issues below as soon as possible.

1: Scope of "Patented Pharmaceutical Articles" -- Which Patent(s) Qualify as valid and unexpired?

Annex subdivision (c)(ii) defines "patented pharmaceutical articles" as pharmaceutical articles and ingredients that are subject to a valid, unexpired U.S. patent and that are listed in the FDA's Orange Book or Purple Book ("The Books").

Issue: The definition conjoins two concepts, (1) patent status and (2) Orange/Purple Book listing, without specifying whether the qualifying patent is one of the specific patents listed against the product in the Orange or Purple Book, or whether any valid, unexpired U.S. patent covering the product and not listed in The Books (including, but not limited to, unlisted process, manufacturing, or method-of-use patents) is considered to validate patent status.
This matters because a product's exclusivity patent, or other listed in The Books may have expired, while another formulation or method-of-use patent remains unexpired but not listed in The Books. Annex I subdivision (c)(ii) does not specify which category of patent controls.

Request: We ask the Department to confirm whether a "valid, unexpired U.S. patent" in Annex I subdivision (c)(ii) refers only to a patent actually listed against the product in the Orange Book or Purple Book and if not, provide additional guidance and information regarding the appropriate patents to qualify this claim.

2: Scope of "Generic Pharmaceutical Articles" for the purposes of Proclamation 11020

Annex I subdivision (c)(iii) first defines "generic pharmaceutical articles" as products "not subject to a valid, unexpired U.S. patent" and "off exclusivity," then separately defines a generic pharmaceutical article as one approved or licensed under a "qualifying application" -- an ANDA under FDCA section 505(j); a section 505(b)(2) application deemed therapeutically equivalent; a biosimilar application

under PHSA section 351(k); or an authorized generic/biological product under FDCA section 505(t), the last of which is expressly conditioned on the product being "imported by a generic or biosimilar manufacturer."

Issue: The definition of "generic pharmaceutical article" joins two potentially different qualifications, the first is a substantive patent/exclusivity test that would sweep in any off-patent, off-exclusivity product regardless of approval pathway (e.g., an off-patent product still marketed under an original NDA) as a 'generic' for the purposes of this Proclamation. The second is an application-specific test tied to four enumerated filing/application approval types. It is unclear whether both must be satisfied conjunctively to qualify as "generic," or whether either is independently sufficient.

Issue: The "imported by a generic or biosimilar manufacturer" condition is, on the text, attached only to the authorized-generic/biological-product pathway ((C)(iii)(d)), it is unclear whether that importer-identity condition was intended to apply only to that pathway, or was meant to apply across all four qualifying-application types, including ANDA and biosimilar approvals where no such condition is textually present.

This matters because some members report classifying off-patent, off-exclusivity products approved under an original **NDA** (not an enumerated pathway) as "generic" for the purposes of this Proclamation on the view that the patent/exclusivity test is the operative substantive standard.

Request: We ask the Department to clarify that meeting either the patent/exclusivity test or the qualifying-application test independently is sufficient for the purposes of heading 9903.04.67 (i.e., that an off-patent, off-exclusivity product approved under an original NDA qualifies as "generic" absent an enumerated qualifying application) and (ii) whether the "imported by a generic or biosimilar manufacturer" condition applies only to authorized generics/biologics under item (c)(iii)(d), or to all four qualifying-application types.

3: Heading 9903.04.66 -- Whether Secretarial Determination Is a Precondition to Self-Classification

Annex I subdivision (h)(iii) extends zero-duty treatment to orphan-designated drugs; nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; CBRN countermeasures; 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.

Issue: It is unclear if the determination for classification under 9903.04.66 for the entire list is subject to the Secretary determining that the imported products meet the jurisdiction or urgent-health-need standard and are subject to a Federal Register publication.

Request: We ask the Department to confirm that identification of a product through satisfaction of the Federal Register notice/CBP notification requirement in Annex I subdivision (h)(iii) is not a precondition for importation of any product under heading 9903.04.66 and that this precondition applies only to the residual "other specialty products/animal health" category. We also request the Department to publish a process and timeline for importers to obtain the required determination, given that heading 9903.04.66 has been operative since July 31, 2026.

4: U.S.-Origin Exemption

Clause 11 of the Proclamation states, without qualification, that "imports of United States-origin pharmaceutical products shall not be subject to the tariffs imposed by this proclamation at this time."

Issue: Annex I implements this exemption through heading 9903.04.68, described only as applying to "pharmaceutical products with an active pharmaceutical ingredient packaged in dosage form that is a product of the United States." The CSMS Guidance restates the narrow, dosage-form-specific description, but separately and independently states, under a standalone "U.S. Origin Pharmaceuticals" heading, that "imports of United States-origin pharmaceutical products are not subject to the tariffs imposed by the Proclamation", repeating Clause 11's unqualified language verbatim.

Request: We ask the Department to confirm (i) whether heading 9903.04.68's dosage-form requirement is in error and not intended to narrow Clause 11's unqualified exemption and if ii) Annex I and the CSMS Guidance for such heading will be corrected to state a single, consistent standard, allowing the importation of US-origin pharmaceuticals without specificity to the API or packaged status to be consistent with the intent of the Proclamation.

5: Applicability of the Proclamation to Pre-Approval, Clinical-Stage, and General R&D Pharmaceutical and Ingredients

Imported articles subject to Headings 9903.04.60, -.61, -.62, -.63, -.64, -.65, must meet the definitions in subdivision (c)(ii) of a “Patented Pharmaceutical article”, articles subject to Heading 9903.04.66 must be for the specific uses provided, articles subject to Heading 9903.04.67 must meet the definition in subdivision (c)(iii) of a “Generic Pharmaceutical article”, articles subject to Heading 9903.04.68 must be of US-Origin, and articles subject to Heading 9903.04.69 are for articles not of subdivisions (c)(i)-(c)(iii).

Issue: The Proclamation, Annex 1, nor CSMS Guidance define what is a “Pharmaceutical product” under subdivision (c)(i) “Pharmaceutical articles”. The following examples may meet the Patent Status test, depending on the clarification to **Issue 1,** but cannot meet the definition of Patented Pharmaceutical as the material is not Orange/Purple Book-listed because there are no approvals to list the

material against. The following are demonstrations purposes and are not all-inclusive:

- **API/Drug product not yet FDA-approved:** does not meet the definition of Patented Pharmaceutical as the material is not Orange/Purple Book-listed because there is no approval to list it against, may have an NDA/BLA application pending.
- **Unapproved API/Drug Product in Phase I, II, III development and clinical studies:** does not meet the definition of Patented Pharmaceutical as the material is not Orange/Purple Book-listed because approval to list it against.
- **General R&D chemicals not yet formulated into, or identified as, a API candidate or drug product candidate.**

Request: We ask the Department to clarify the correct classification for each of the three scenarios above -- specifically, i) provide a definition for “pharmaceutical product” under subdivision (c)(i) “Pharmaceutical articles” and ii) confirm whether the above and similar examples should fall under the residual heading 9903.04.69 as not a "pharmaceutical article" at all.

6: Orphan Drug Exemption -- "All” Approved Indications vs. Indication-Specific Standard

Clause 3(d) of the Proclamation grants zero-duty treatment to "drugs and associated ingredients, where all approved indications are designated as orphan pursuant to the Orphan Drug Act." Annex I (h)(iii) implements this for "drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act."

Issue: These statements are not equivalent. The Proclamation's phrasing, "where all approved indications are designated as orphan […]", reads as a product-level, conjunctive test: the imported product or ingredient qualifies only if every one of its approved indications carries orphan designation. Annex I's phrasing, "for all approved indications that are designated as orphan", is read as an indication-

specific treatment, applying to imports of medicament intended for said-orphan status indication.

Request: We ask the Department to (i) reconcile the "all approved indications" language in the Proclamation with the indication-specific language in Annex I; (ii) clarify whether a drug with multiple approved indications, some orphan-designated and some not, is eligible for heading 9903.04.66 in whole, in part, or not at all; and (iii) if indication-specific specify what documentation CBP will require to substantiate an indication-specific exemption claim. It is important to note that at the time of importation the intended use by indication is most unknown or can be used to various indications with no delineation of final distribution and use.

7: Annex IV Zero-Rated Products vs. Annex I Dutiable Products — Direct Overlap in HTSUS Subheadings 3002.13–3002.15

Text at issue: The Proclamation's preamble (paragraph 7) states that "pharmaceutical products and ingredients that are subject to the section 232 zero tariff at this time are listed in Annex IV to this proclamation." Annex IV describes itself as the list of HTSUS codes "not covered under the Annex I actions of this proclamation" that carry a zero Section 232 rate, and that are also excepted from the separate reciprocal tariff surcharge under Proclamation 11012.

Issue: Annex IV lists subheadings 3002.13 through 3002.15 as zero-rated and, by its own terms, outside the scope of Annex I's actions. Annex I's own enumerated Note 40(c) list, however, separately includes specific statistical suffixes within those same subheadings — 3002.13.0010, 3002.13.0090, 3002.14.0010, 3002.14.0090, 3002.15.0011, and 3002.15.0091 — as codes subject to the Proclamation's tariffs. The identical subheadings therefore appear on both lists at once: Annex IV treats them as zero-rated and expressly outside Annex I's coverage, while Annex I treats them as within scope and dutiable at the applicable patented/generic/etc. rate. The CSMS Guidance does not address or reconcile this overlap; its heading-by-heading walkthrough of 9903.04.60–9903.04.69 does not reference Annex IV at all.

Request: We ask the Department and CBP to confirm which statistical suffixes within HTSUS subheadings 3002.13, 3002.14, and 3002.15 are properly treated as Annex IV zero-rated products outside the scope of the Section 232 pharmaceutical tariff, and which, if any, remain dutiable under Annex I, and to reconcile the direct conflict between the two annexes for these codes.

8: Foreign Trade Zone Privileged Foreign Status -- Loss of the Pre-Existing Inverted-Tariff Benefit, Stacked With the New Section 232 Duty

Clause 13 of the Proclamation, restated verbatim in the CSMS Guidance's "Foreign Trade Zone" section, provides that any product subject to a duty imposed by the Proclamation that is admitted into a U.S. Foreign Trade Zone on or after the effective date -- other than merchandise eligible for "domestic status" under 19 CFR 146.43 -- "must be admitted as 'privileged foreign status' as described in 19 CFR 146.41 and will be subject upon entry for consumption to any ad valorem rates of duty related to the classification under the applicable HTSUS subheading."

Issue: Under standard FTZ practice, privileged foreign ("PF") status fixes the applicable tariff classification and duty rate as of the date merchandise is admitted into the zone, based on its condition at admission -- unlike non-privileged foreign ("NPF") status, under which classification and rate are determined based on the merchandise's condition at the time of withdrawal for consumption.

Pharmaceutical manufacturers have long used NPF status specifically to capture a well-known "inverted tariff" in this industry: many APIs and bulk drug substances carry a positive Column 1 (MFN) duty rate (commonly around 6.5% under standard organic-chemical provisions), while the corresponding finished, dosage-form pharmaceutical product is frequently classified duty-free under the tariff schedule's pharmaceutical provisions. Under NPF status, an importer could admit dutiable API into the zone, manufacture it into the duty-free finished product, and withdraw it for consumption at the finished product's zero rate.

By mandating PF status for merchandise subject to the new duties set forth in this Proclamation, inverted tariff benefit is eliminated as PF status locks in the classification and rate of the merchandise as admitted -- i.e., the dutiable raw material or API -- so the finished product's duty-free classification can no longer be captured upon withdrawal.

This is a cost separate from, and in addition to, the new tariff implemented with this Proclamation: importers using FTZs for covered pharmaceutical merchandise now stand to lose the pre-existing Column 1 inverted-tariff benefit (paying the input material's ~6.5% rate rather than the finished product's 0% rate) on top of whatever new duty applies. Furthermore, the forced use of PF status subjects companies with Onshoring and/or MFN agreements who should not be subject to any duties until January of 2029 to now be subject to the MFN column 1 6.5% duty regardless of the relief from the Section 232 duties.

This also raises a timing question the Proclamation, Annex I, and the CSMS Guidance do not address: "patented," "generic," orphan, and U.S.-origin as the status under Annex I subdivision (c) and (h) can all change over the period merchandise is held and processed in a zone -- a patent can expire, a product can receive FDA approval, an orphan designation can attach. It is unclear whether the sub-classification under headings 9903.04.60-.69 is likewise fixed as of the date of admission, consistent with ordinary PF mechanics, or determined as of the date of entry for consumption, consistent with how the CSMS Guidance otherwise describes these headings as applying to entries.

Request: We ask the Department to confirm (i) whether Clause 13's mandatory privileged foreign status requirement is intended to eliminate FTZ operators' ability to use non-privileged foreign status to capture the pre-existing inverted-tariff benefit between dutiable API/raw material and duty-free finished pharmaceutical product; (ii) whether this consequence, which operates independently of the new duty, was intended; and (iii) whether the Section 232 sub-classification of merchandise under headings 9903.04.60-9903.04.69 is fixed as of the date of admission to the zone or determined as of the date of entry for consumption, given

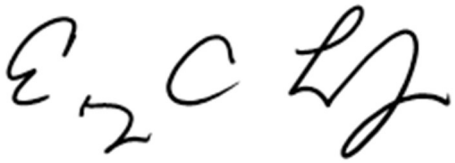
that a product's patent, approval, and designation status may change materially while the merchandise is held in privileged foreign status.

Conclusion

AAEI recognizes the Department's significant undertaking in implementing Proclamation 11020 on an accelerated timeline and appreciates the guidance already provided in CSMS #69395344. Given the compliance obligations already in effect, and the significant duty exposure at stake across our membership (0% vs. 100% ad valorem, depending on classification), we respectfully request a written response or supplemental public guidance addressing the issues above at the Department's earliest opportunity.

AAEI appreciates your consideration of these important, unresolved matters. We welcome the opportunity to meet with Commerce staff to discuss practical implementation solutions that advance national security objectives while promoting predictable compliance.

Respectfully submitted,



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