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WHITE PAPER

Navigating Harmonized Tariff Schedule of the United States Classification: A Strategic Guide for Small Biotechs Importing Investigational Medicinal Products



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Introduction

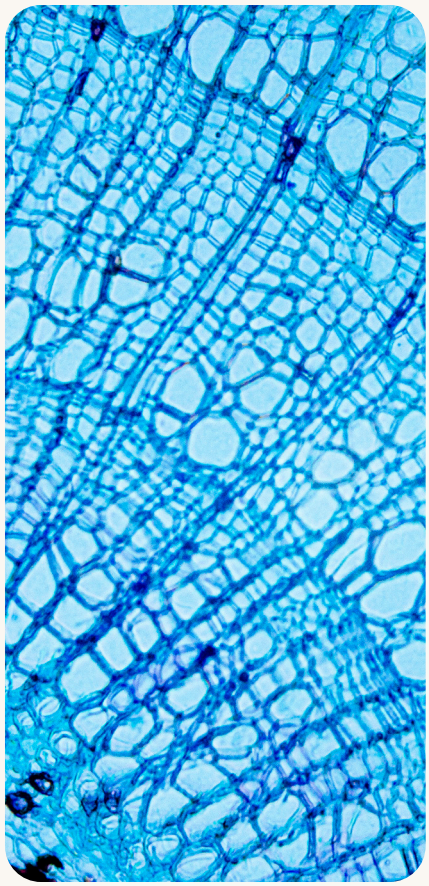


For many emerging biotechnology companies, customs classification is often viewed as an administrative exercise delegated to a customs broker shortly before a shipment leaves a manufacturing site. In reality, tariff classification decisions can have significant implications for cash flow, duty exposure, customs audits, clinical trial timelines, and overall supply chain risk. As development-stage biotechs increasingly rely on global manufacturing networks, importing investigational medicinal products (IMPs), active pharmaceutical ingredients (APIs), comparators, placebos, and clinical trial materials has become a routine part of business operations. Yet few small companies possess dedicated trade compliance expertise. The result is that tariff classifications are frequently inherited from suppliers, copied from prior entries, or selected without a complete understanding of how the Harmonized Tariff Schedule of the United States (HTSUS) works. This approach can create substantial risk. According to U.S. Customs and Border Protection (CBP), importers are responsible for exercising reasonable care when classifying imported merchandise and providing information necessary for customs authorities to properly assess duties and enforce applicable laws. For small biotech companies operating with limited resources, successful customs compliance is therefore not about finding a tariff code with the lowest duty rate.

It is about establishing a defensible classification strategy that can withstand regulatory scrutiny while supporting efficient movement of clinical supplies. [1,2]

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Understanding What HTSUS Classification Really Means



One of the most common misconceptions within biotech organizations is that an investigational product automatically qualifies for a specific tariff classification because it is intended for clinical use.

Customs classification does not work that way.

HTSUS classification is based primarily on the condition of the merchandise at the time of importation. Customs authorities evaluate what the product actually is, how it is formulated, how it is packaged, and how the tariff schedule describes similar goods. The fact that a product is investigational may be relevant in certain circumstances, but it does not automatically determine classification. This distinction is particularly important because two products used in the same clinical trial may require entirely different classifications. An antibody drug substance, a formulated bulk drug product, a finished vial presentation, and a placebo kit may all support the same protocol yet fall under different tariff provisions. Consequently, companies should avoid thinking of customs classification as a clinical development activity. Instead, it should be viewed as a technical analysis of the imported article itself.[3,4]

Why Early Classification Planning Matters

Many biotech companies first encounter tariff classification issues when preparing their inaugural clinical supply shipment. By that point, shipment schedules are often compressed, manufacturing slots have closed, and patient enrollment timelines are approaching. A rushed classification decision can generate operational problems that extend far beyond duties. An incorrect classification may trigger customs examinations, entry corrections, regulatory inquiries, or delays in product release. In severe cases, classification disputes can surface years later during customs audits, forcing companies to reconstruct documentation long after personnel, systems, and vendors have changed.

The financial consequences can also be significant. While many pharmaceutical products enter the United States duty-free under Chapter 30, customs treatment is determined by more than the ordinary duty rate. Additional tariffs, Chapter 99 provisions, country-of-origin considerations, and special regulatory requirements can all affect the landed cost of imported materials. The United States International Trade Commission (USITC) continues to update pharmaceutical tariff provisions within the HTSUS, underscoring the need for periodic review rather than reliance on historical classifications. For these reasons, classification decisions should be made during supply chain planning, not immediately before shipment.[5]

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Product Classification Versus Special Tariff Programs

An area that causes frequent confusion involves the relationship between standard pharmaceutical classifications and special Chapter 99 provisions.

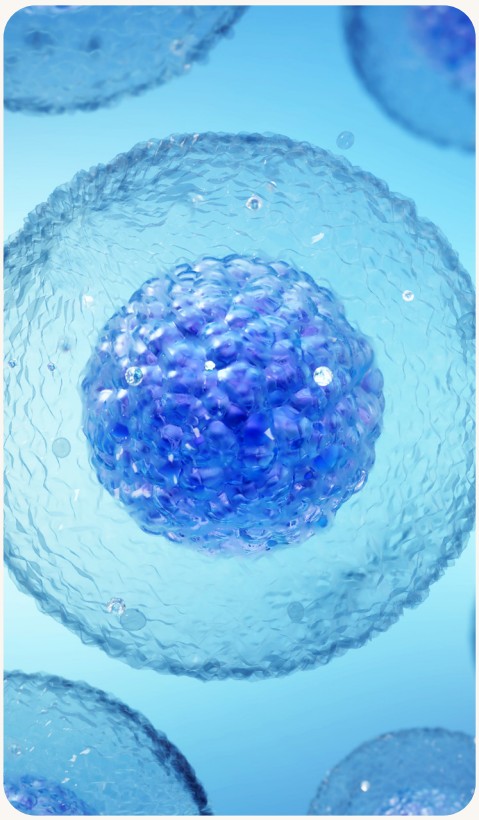
Many sponsors assume that Chapter 99 provisions provide a preferred classification for investigational products. In reality, Chapter 99 provisions are generally supplemental to the underlying classification rather than replacements for it. The first question customs authorities ask is: What is the imported product? Only after that question is answered do they typically consider whether special provisions, exclusions, temporary measures, or additional duties apply. This distinction has become particularly relevant as biotechnology companies evaluate provisions such as HTSUS 3003.90.01.90 and HTSUS 9903.04.70. While both can be associated with favorable duty treatment under certain circumstances, they function differently. A Chapter 30 classification generally derives from the characteristics of the product itself. By contrast, certain Chapter 99 provisions may require an importer to demonstrate that specific conditions relating to use, eligibility, or origin have been satisfied.

From a risk-management perspective, classifications based on the inherent nature of the product are often more stable than those dependent upon proving future or intended use. This does not mean that Chapter 99 provisions should be avoided. Rather, they should be approached as additional analytical considerations rather than substitutes for a complete classification exercise.[4,6] [6,7,8]



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The Unique Challenges of Biologic Therapies



Biologic products create additional complexity because their scientific descriptions do not always align neatly with customs terminology. Today's biotech pipeline contains monoclonal antibodies, antibody-drug conjugates, recombinant proteins, cell therapies, gene therapies, cytokines, and other highly specialized products. Chapter 30 includes specific provisions addressing immunological products and identifies a variety of biologically derived materials, including monoclonal antibodies, antibody conjugates, interleukins, interferons, chemokines, growth factors, hematopoietins, and colony-stimulating factors. As a result, companies should be cautious about applying a single classification methodology to their entire development portfolio. Products that appear similar from a clinical perspective may require different treatment under the tariff schedule. The issue becomes even more complicated when a company is simultaneously importing drug substance, formulated bulk product, finished dosage forms, and clinical kits. Although each item supports the same development program, customs authorities may view them as distinct products with separate classification analyses.[7]

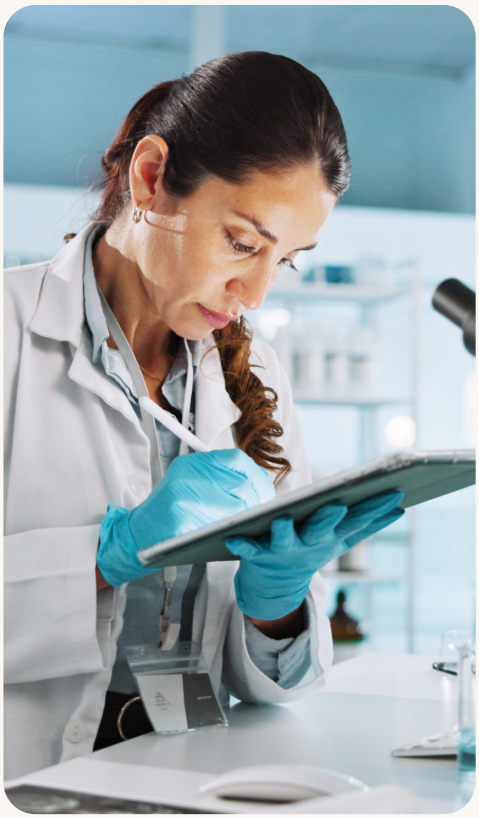


Clinical Trial Materials Are Not All the Same

Another common source of confusion involves clinical trial supplies. Sponsors often group comparators, placebos, blinded kits, and investigational products under a general description such as "clinical trial materials." However, customs authorities generally evaluate individual imported articles rather than protocol categories. Chapter 30 contains specific references to placebos and blinded clinical trial kits used in recognized clinical trials. These provisions highlight the importance of understanding the actual configuration of a shipment rather than relying solely on a protocol designation. For example, a shipment containing an active comparator, placebo tablets, administration materials, and patient kits may require significantly more analysis than a shipment consisting only of bulk drug product. The lesson for supply chain teams is straightforward: the term "clinical supply" is not a customs classification.[7]

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The Importance of Documentation



Perhaps the most overlooked aspect of customs compliance is documentation.

A classification may seem obvious at the time a shipment is imported, but customs reviews frequently occur months or years later. During that period, companies may undergo mergers, personnel turnover, contract manufacturer changes, or system migrations. When customs authorities request justification for a classification decision, memories are rarely sufficient. Small biotech companies should therefore maintain a classification dossier for each imported product. The objective is not to create unnecessary paperwork but to preserve the rationale supporting the classification. An effective dossier should tell a complete story. It should explain what the product is, who manufactured it, how it was formulated, how it was packaged, why a specific HTSUS provision was selected, and which supporting documents were reviewed.
The strongest classification files combine technical, regulatory, and commercial information into a single reference package that can be readily accessed by supply chain personnel, finance teams, customs brokers, and legal advisors.

Managing the Relationship with Customs Brokers

Many emerging companies assume their customs broker is responsible for selecting tariff classifications. While brokers play a critical role in filing entries, the importer ultimately bears responsibility for the accuracy of customs declarations. CBP's informed compliance guidance makes clear that importers must exercise reasonable care regarding classification decisions. This does not diminish the value of brokers. Rather, it highlights the need for collaboration. A customs broker cannot independently determine whether a vial contains a monoclonal antibody, a recombinant protein, a placebo, or a chemically synthesized small molecule unless the sponsor provides sufficient information. The best importers therefore treat brokers as strategic partners. They supply detailed product information, review proposed classifications, discuss unusual products in advance, and periodically reassess established classifications as development programs evolve. When a broker becomes the only repository of customs knowledge, organizational risk increases dramatically.[1,2]



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Integrating Customs and FDA Requirements

A final consideration is the relationship between customs compliance and FDA compliance.

Investigational drug products entering the United States are generally subject to FDA requirements relating to Investigational New Drug (IND) applications, labeling, consignees, and authorized clinical use. FDA reviews and verifies entry information against its systems during the import process. Although FDA and CBP operate under separate legal authorities, inconsistencies between customs declarations and FDA submissions frequently attract unwanted attention. The most effective import programs therefore align customs and regulatory data. Product descriptions, consignee information, intended use declarations, IND references, and shipment documentation should tell a consistent story across all government agencies involved in the import process.[9,10]

Currency note:

HTSUS provisions and additional-duty programs can change frequently. The classifications and tariff references in this article should be validated against the current HTSUS and applicable CBP instructions at the time of entry.[5,6]

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Conclusion

For small biotechnology companies, customs classification should be viewed as a strategic supply chain capability rather than a clerical task.

The consequences of classification decisions extend well beyond duty payments and can affect clinical trial continuity, regulatory compliance, customs audits, and overall operational efficiency. The most successful organizations recognize that HTSUS classification begins with understanding the product itself. They separate product classification from Chapter 99 eligibility, maintain strong documentation, periodically review classifications as development programs evolve, and engage experienced customs professionals when uncertainty exists. Most importantly, they build customs compliance into supply chain planning early rather than waiting until a shipment reaches the border. In today's environment of evolving pharmaceutical trade policies, increasing scrutiny of imported healthcare products, and growing reliance on global manufacturing networks, a well-documented and defensible HTSUS strategy can be as valuable to a biotech company as any other component of its clinical supply chain.



REFERENCES

1. U.S. Customs and Border Protection (CBP). "Reasonable Care." Informed Compliance Publication. Updated January 7, 2026.
2. U.S. Customs and Border Protection (CBP). "Informed Compliance Publications," including Tariff Classification and Recordkeeping guidance. Updated June 1, 2026.
3. Harmonized Tariff Schedule of the United States, General Rules of Interpretation, 2026 HTS Revision 21. U.S. International Trade Commission (USITC).
4. Harmonized Tariff Schedule of the United States, Chapter 99, U.S. Notes and Statistical Notes. USITC, 2026.
5. U.S. International Trade Commission (USITC). "Harmonized Tariff Schedule 2026, Revision 21." Accessed October 19, 2026.
6. U.S. Customs and Border Protection (CBP). CSMS #70054007, "Updated Guidance: Section 232 Duties on Imports of Pharmaceutical Articles and Ingredients," September 28, 2026.
7. U.S. International Trade Commission (USITC). HTS Chapter 30, Pharmaceutical Products, including headings 3002, 3003, 3004, and provisions for clinical-trial placebos and blinded kits. 2026 HTS Revision 21.
8. U.S. Department of Commerce, Bureau of Industry and Security. "Guidance and Procedures for Implementing Tariff Adjustments for Specialty Pharmaceuticals and Associated Pharmaceutical Ingredients," 91 Fed. Reg. 60360, September 23, 2026.
9. U.S. Food and Drug Administration (FDA). "Importing Investigational New Drugs." Content current June 15, 2026.
10. U.S. Food and Drug Administration (FDA). "Importing Human Drugs."

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