SUBJECT: H963778F - CLASSIFICATION PHARMACEUTICAL PRODUCTS


U.S. CUSTOMS SERVICE GENERAL NOTICE

GUIDANCE CONCERNING THE TARIFF CLASSIFICATION OF PHARMACEUTICAL PRODUCTS IMPORTED FOR CLINICAL RESEARCH

AGENCY: U.S. Customs Service, Department of the Treasury

ACTION: Guidance concerning the tariff classification of pharmaceutical products imported for clinical research.

SUMMARY: This notice sets forth Customs views regarding the classification, under the Harmonized Tariff Schedule of the United States (HTSUS), of pharmaceutical products, imported in bulk form or dosage form for clinical research, for which no New Drug Application has been approved by the Food and Drug Administration.

FOR FURTHER INFORMATION CONTACT: Michael McManus, General Classification Branch, Office of Regulations & Rulings (202) 927-2326.

SUPPLEMENTARY INFORMATION: Background

On August 4, 1999, Customs published a notice in the CUSTOMS BULLETIN, Vol. 33, No. 31, which advised the public that Customs was soliciting comments regarding the classification, under the HTSUS, of pharmaceutical products, imported in bulk form or dosage form, for which no New Drug Application has been approved by the Food and Drug Administration (FDA), and which are therefore unavailable as medicines outside of clinical trials. This notice acknowledged the existence of inconsistent tariff classification rulings and stated Customs intention to revoke certain rulings so that similar products in like stages of the FDA approval process are treated in a like manner. Comments were requested on or before September 3, 1999. This comment period was later extended to October 4, 1999.

Twenty-one comments were received in response to this notice. Each of the comments argued in favor of classifying the goods as drugs or medicaments. Most of the comments pertained to the effects of other agency decisions upon Customs tariff classification decisions, the scope of the term "drug" as used in the Food, Drug and Cosmetic Act, and the United States’ international obligations under the International Convention on the Harmonized Commodity Description and Coding System and the Agreement Establishing the World Trade Organization (WTO Agreement).

Other Agency Decisions

Comment. Several commenters point to abundant precedent stating that tariff classification is not
controlled by the decisions of agencies other than Customs and that FDA approval is therefore irrelevant.

Response. Other agency decisions do not control Customs classification decisions. However, where tariff classification is dependent upon the principal use of an item, and use is regulated by some other governmental agency, Customs must be cognizant of such regulation. An agency other than Customs can affect whether merchandise falls within a principal use provision where it can regulate the use of such merchandise. Headquarters Ruling ="../Rulings/957522.asp"MACROBUTTONHtmlResAnchorRulings957522.asp> HQ 957522, dated May 24, 1995, is cited as precedent for the irrelevance of FDA approval. In that case, latex gloves imported for non-medical purposes were classified by Customs as medical gloves of heading 4015, HTSUS, as they were indistinguishable from gloves used for medical purposes. However, if the provision for medical gloves were a use provision ("gloves used for medical purposes"), and FDA regulations barred the imported gloves from such use, they would fall outside the scope of the provision. The latter case is more closely analogous to the classification of pharmaceuticals undergoing clinical trials than HQ ="../Rulings/957522.asp"MACROBUTTONHtmlResAnchorRulings957522.asp>HQ 957522.

The Definition of "Drug" Found in the Food, Drug, and Cosmetic Act

Comment. Commenters also argue that if FDA decisions are relevant to Customs classification, then pharmaceutical products undergoing clinical trials should be considered "drugs" because the FDA statute defines that term very broadly.

Response. The definition of the term "drug" found in the Food, Drug and Cosmetic Act is specifically limited to that Act. 21 U.S.C. 321(g)(1) ("For the purposes of this Act...[t]he term "drug" means...") (emphasis added). Further, as a general rule, terms defined in non-tariff statutes do not determine the meaning of the term for tariff purposes. Amersham Corp. v. United States, 5 CIT 49, 56, 564 F.Supp. 813 (1983). As above, other agency decisions are relevant to tariff classification only where the tariff provision is a use provision and the other agency decision limits certain uses of the imported merchandise. Thus, the FDA definition of "drug" is not coterminous with the term as used in Chapter 29 of the HTSUS.

International Obligations

Comment. Several commenters argue that classification of chemical compounds undergoing clinical trials outside of "drug" provisions violates U.S. international obligations. Specifically, commenters suggest that such a classification practice would violate U.S. obligations under the WTO Agreement and the International Convention on the Harmonized Commodity Description and Coding System (HS Convention).

Response. In 1994, as a result of the Uruguay Round negotiations, the U.S. entered into Schedule XX - USA. Schedule XX represents the tariff obligations of the United States assumed under the WTO Agreement and includes the Pharmaceutical Appendix.

The WTO Agreement and each of the Agreements appended thereto were approved by Congress
which enacted necessary and appropriate implementing legislation along with a "statement of
administrative action." This "statement of administrative action" states that "[d]uring the
Uruguay Round, the U.S. sought the reciprocal elimination of duties among major trading
countries in a wide range of sectors of key interest to U.S. firms. This zero-for-zero initiative
consisted of the following sectors: pharmaceuticals...[i]n respect to pharmaceutical products, the
U.S. and 16 other major trading countries have agreed on the reciprocal elimination of tariffs on
existing products and agreed not to impose duties on new pharmaceutical products as they are
developed in the future. The President would use section 111(b) [inclusion in the Pharmaceutical
Appendix] to grant duty-free tariff treatment to those new products." Administrative Action
U.S.C.C.A.N., 4064, 4073-4 (approved 19 U.S.C 3511 (a)(2)).

In regard to the Pharmaceutical Appendix, Schedule XX states as follows:

This Appendix includes the following goods: 1. All goods classified in Harmonized System (HS)
Chapter 30 or in HS heading 2936, 2937, 2939 or 2941, except dihydrostreptomycin and salts,
esters and hydrates thereof. 2. Pharmaceuticals having an International Non-Proprietary Name
(INN) assigned by the World Health Organization listed in Table 1. 3. Salts, esters and hydrates
of pharmaceutical products described by the combination of an INN active ingredient listed in
Table 1 with a prefix or suffix listed in Table 2, except monosodium glutamate, provided such
salt, ester or hydrate is classified in the same HS 6-digit headings as the INN active ingredient. 4.
Salts, esters and hydrates of INN active ingredients not classified in the same 6-digit heading as
the INN active ingredient, listed in Table 3. 5. Chemical intermediates listed in Table 4 used for
the manufacture of pharmaceuticals.

The Pharmaceutical Appendix was incorporated into the HTSUS by Presidential Proclamation.
See Proclamation No. 6763, 60 Fed. Reg. 1007 (1994). This Proclamation also added General
Note 13 to the HTSUS. General Note 13 states that whenever a rate of duty of "Free" followed
by the symbol "K" in parentheses appears in the "Special" column for a tariff provision, products
classifiable in such provision shall be entered free of duty, provided that such product is listed in
the Pharmaceutical Appendix.

The Pharmaceutical Appendix does not broaden or narrow the scope of the "drugs" provisions.
There are 54 eight-digit "drugs" provisions within Chapter 29, HTSUS, which are subject to
duty. Each of these provisions has a "K" in the "Special" column, indicating that drugs which are
included in the Pharmaceutical Appendix are duty-free while drugs not included in the
Pharmaceutical Appendix are subject to duty.

The statement of administrative action and subsequent presidential proclamations (adding items
to the Pharmaceutical Appendix) indicate that inclusion within the Pharmaceutical Appendix is
the means by which duty-free treatment is to be extended to new pharmaceuticals. A product
need not be considered a "drug" in order to be included in the Pharmaceutical Appendix.

Further, Congress provided no indication that it intended to modify the drug provisions of
Chapter 29. The "drugs" provisions of Chapter 29 have a specific meaning as enunciated in
Lonza, Inc. v. U.S., 46 F.3d 1098 (Fed. Cir. 1995), independent of the trade concessions agreed
to as a result of multilateral trade negotiations embodied within Schedule XX. The various drug provisions of Chapter 29 are not coterminous with the Pharmaceutical Appendix. The scope of the term "drugs" is unaffected by the 1994 trade accords.

In a similar vein, numerous commenters suggest that Customs recent practice is violative of the HS Convention. This agreement states that each party to the convention "shall not modify the scope of the sections, chapters, headings or subheadings of the System." However, we note that the subheadings of Chapter 29 which contain the term "drugs" are not a part of the international nomenclature; rather they are U.S. subdivisions of international six-digit subheadings. A change in classification from one national subheading to another, both within the same international subheading, does not implicate the HS Convention.

Issues Presented

Pharmaceutical products may be imported in various forms; thus, several distinct classification issues are presented:

1. How should unmixed (pure) compounds, imported in bulk for use in clinical trials be classified for tariff purposes? That is, should such merchandise be considered "drugs" for tariff classification purposes?

2. How should a mixture of compounds, imported in bulk for use in clinical trials, be classified? That is, are such mixtures "medicaments" of heading 3003, HTSUS?

3. How should pharmaceutical products imported in dosage form for use in clinical trials be classified? That is, should such merchandise be considered "medicaments" of heading 3004, HTSUS?

Law and Analysis

Merchandise imported into the United States is classified under the HTSUS. Tariff classification is governed by the principles set forth in the General Rules of Interpretation (GRIs) and, in the absence of special language or context which requires otherwise, by the Additional U.S. Rules of Interpretation. The GRIs and the Additional U.S. Rules of Interpretation are part of the HTSUS and are to be considered statutory provisions of law for all purposes.

GRI 1 requires that classification be determined first according to the terms of the headings of the tariff schedule and any relative section or chapter notes and, unless otherwise required, according to the remaining GRIs taken in order. GRI 6 requires that the classification of goods in the subheadings of headings shall be determined according to the terms of those subheadings, any related subheading notes and mutatis mutandis, to the GRIs. Further, only those subheadings at the same level of indentation are comparable. In understanding the language of the HTSUS, the Explanatory Notes (ENs) of the Harmonized Commodity Description and Coding System may be utilized. The ENs, although not dispositive or legally binding, provide a commentary on the scope of each heading, and are generally indicative of the proper interpretation of the HTSUS. See, T.D. 89-80, 54 Fed. Reg. 35127 (August 23, 1989).
Chapter 29 of the HTSUS, with exceptions inapplicable here, provides only for "separate chemically defined organic compounds, whether or not containing impurities." Note 1(a), Chapter 29, HTSUS. That is, mixtures of an organic compound with an inorganic compound or with another organic compound are excluded. Thus, an unmixed compound, imported in bulk for incorporation within a pharmaceutical product falls in Chapter 29 while a mixture of compounds, whether or not in dosage form, is excluded.

As the term "drugs," as used in Chapter 29, HTSUS, is not coterminous with that term as used in the Food, Drug, and Cosmetic Act, is not modified by international trade agreements entered into subsequent to adoption of the HTSUS, nor is its scope enlarged by the HS Convention, we return to Lonza to aid in determining whether separately defined chemical compounds, imported in bulk for clinical testing, are "drugs" within the meaning of the tariff.

The first part of the Lonza test requires that a substance have "therapeutic or medicinal" properties. "Therapeutic" and "medicinal" have been judicially construed to mean "having healing or curative powers" and "curing, healing, or relieving," respectively. Prior to beginning clinical trials, a substance undergoes substantial in vitro and animal testing. Clinical trials go forward only where previous testing indicates the presence of beneficial pharmaceutical action. Thus it can plausibly be asserted that substances entering Phase I of the clinical trial process have, or are likely to have, therapeutic or medicinal properties.

The second requirement for classification as "drugs" under Lonza is that substances be "chiefly used as medicines or as ingredients in medicines." The phrase "chiefly used" indicates that classification as a drug depends upon principal use. "A tariff classification controlled by use (other than actual use) is to be determined in accordance with the use in the United States at, or immediately prior to, the date of importation...." Additional U.S. Rule of Interpretation 1(a), HTSUS. The Investigational New Drug Application (IND) process consists of several "phases." 21 CFR 312.21. In Phase I, a substance is administered to a relatively small number of usually healthy volunteers to determine "the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 CFR 312.21 (a)(1). In Phase II, the substance is administered to a larger group of affected people to determine "the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." 21 CFR 312.21 (b). Phase III trials are similar to Phase II with a larger test group. Upon completion of Phase III trials a party may seek approval of a new drug application (NDA). An NDA is approved where the substance is found to be safe for administration to humans and efficacious in the treatment of some ailment. Upon approval of an NDA, the substance becomes available for physicians to prescribe to patients.

In general, a compound which is in the FDA trial process is unavailable for use in the U.S. outside of those trials. The sole use of such a substance is therefore determined by the clinical trials. Phase I clinical trials typically involve volunteers who are not afflicted with the disease or ailment which the substance is intended to treat. Thus, for the duration of Phase I trials, the issue narrows to the following: Is a chemical compound, given to healthy human beings primarily to determine the side-effects of such compound, a medicine or ingredient in medicine? The term "medicine" is not defined in the tariff or the Explanatory Notes. The dictionary defines
"medicine" as "a substance or preparation used in treating disease." Webster’s Third New International Dictionary. The better argument seems to be that chemical compounds, administered to humans in Phase I of the FDA trial process, are not used to treat disease, are not medicines, and are not drugs within the scope of Chapter 29. They are merely research compounds. However, compounds in Phase II and III of the clinical trial process are administered to affected patients in the hope that such compounds will act to cure or alleviate the patients’ ailments. Thus, compounds in these latter stages of clinical trials are used to treat disease, are medicines, and should be considered drugs.

Chapter 30 of the HTSUS includes two headings which provide for "medicaments." Heading 3003, HTSUS, provides for "[m]edicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale." Heading 3004, HTSUS, reads "[m]edicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale." Thus mixed medicaments in bulk form fall in heading 3003, while any medicament in dosage form, mixed or unmixed, falls in heading 3004.

Unlike the eight-digit "drugs" subheadings of Chapter 29, HTSUS, headings 3003 and 3004, HTSUS, are part of the international nomenclature and each contracting party to the HS Convention has an obligation to refrain from modifying the scope of such headings.

"Medicament" is not defined in the tariff, however the language of headings 3003 and 3004 gives some indication as to its intended scope. Both medicament provisions contain the phrase "for therapeutic or prophylactic uses." There is one reported case that briefly discusses the term "medicament." In H. Reisman Corp. v. U.S., 17 CIT 1260 (1993), the court held that a solution containing vitamin B-12, used as an ingredient in animal feed, was excluded from classification as a medicament (of heading 3003) because "the merchandise is not used in a therapeutic or prophylactic manner beyond the purposes provided by any nutrient, including ordinary grain feed or food of any kind." H. Reisman at 1260. Neither the Explanatory Notes to heading 3003 nor 3004 explicitly define "medicament;" however, they do include numerous examples of merchandise falling within this heading. One such example is "[p]reparations containing a single pharmaceutical substance together with an excipient, sweetening agent, agglomerating agent, support, etc." EN 30.03(2).

In 1998 there was a proposal before the Harmonized System Review Sub-Committee of the World Customs Organization to classify products as medicaments based on "the availability of a registration certificate confirming the fact that a product has been registered as a pharmaceutical at a national level." WCO Doc. 41.909. After discussion it was found that there was no support for the proposal since the criteria might vary from country to country, moreover, it was felt that such an approach would "not be in agreement with the provisions of the Harmonized System." See Annex B/7 to Document 41.920, Report of the HS Review Sub-Committee, 17th Session, January 1998.

Accordingly, although there is some ambiguity as to the precise meaning of "medicament," the
Explanatory Notes, the H. Reisman case, and the discussion at the Harmonized System Review Sub-Committee suggest that the scope of these provisions is slightly broader than the "drugs" provisions of Chapter 29. Thus, mixtures of compounds, imported in bulk for use in clinical trials, are classified in heading 3003, and pharmaceutical products, imported in dosage form for use in clinical trials, are classified in heading 3004.

Determination

1. Unmixed (pure) compounds, imported in bulk for use in Phase I of clinical trials should not be classified as "drugs" of Chapter 29, HTSUS. Unmixed (pure) compounds, imported in bulk for use in Phase II or Phase III of clinical trials should be classified as "drugs" of Chapter 29, HTSUS.

2. Mixtures of compounds, imported in bulk for use in any phase of clinical trials, should be classified as "medicaments" of heading 3003, HTSUS.

3. Pharmaceutical products imported in dosage form for use in clinical trials should be classified as "medicaments" of heading 3004, HTSUS.

Rulings issued subsequent to publication of this notice will be decided in keeping with this determination. Further, In accordance with 19 U.S.C 1625, Customs will revoke any prior rulings that are inconsistent with this determination. Importers of pharmaceutical products for clinical research are directed to classify such merchandise in the manner indicated above. Requests for binding rulings regarding such products should be addressed to Customs National Commodity Specialist Division as per 19 CFR 177.2. This notice should not be construed to affect the tariff classification of products not undergoing clinical trials under an IND.

Dated: May 4, 2000

John Durant, Director
Commercial Rulings Division