

# Bureau of Customs and Border Protection

## *General Notices*

### **QUARTERLY IRS INTEREST RATES USED IN CALCULATING INTEREST ON OVERDUE ACCOUNTS AND REFUNDS ON CUSTOMS DUTIES**

**AGENCY:** Customs and Border Protection, Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This notice advises the public of the quarterly Internal Revenue Service interest rates used to calculate interest on overdue accounts (underpayments) and refunds (overpayments) of customs duties. For the calendar quarter beginning October 1, 2004, the interest rates for overpayments will be 4 percent for corporations and 5 percent for non-corporations, and the interest rate for underpayments will be 5 percent. This notice is published for the convenience of the importing public and Customs and Border Protection personnel.

**EFFECTIVE DATE:** October 1, 2004.

**FOR FURTHER INFORMATION CONTACT:** Trong Quan, National Finance Center, Collections Section, 6026 Lakeside Boulevard, Indianapolis, Indiana 46278; telephone (317) 614-4516.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85-93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of customs duties must be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621 and 6622. Section 6621 was amended (at paragraph (a)(1)(B) by the Internal Revenue Service Restructuring and Reform Act of 1998, Public Law 105-206, 112 Stat. 685) to provide different interest rates applicable to overpayments: one for corporations and one for non-corporations.

The interest rates are based on the Federal short-term rate and determined by the Internal Revenue Service (IRS) on behalf of the

Secretary of the Treasury on a quarterly basis. The rates effective for a quarter are determined during the first-month period of the previous quarter.

In Revenue Ruling 2004-92, the IRS determined the rates of interest for the calendar quarter beginning October 1, 2004, and ending December 31, 2004. The interest rate paid to the Treasury for underpayments will be the Federal short-term rate (2%) plus three percentage points (3%) for a total of five percent (5%). For corporate overpayments, the rate is the Federal short-term rate (2%) plus two percentage points (2%) for a total of four percent (4%). For overpayments made by non-corporations, the rate is the Federal short-term rate (2%) plus three percentage points (3%) for a total of five percent (5%). These interest rates are subject to change for the calendar quarter beginning January 1, 2005, and ending March 31, 2005.

For the convenience of the importing public and Customs and Border Protection personnel the following list of IRS interest rates used, covering the period from before July of 1974 to date, to calculate interest on overdue accounts and refunds of customs duties, is published in summary format.

<u>Beginning Date</u>	<u>Ending Date</u>	<u>Under-payments (percent)</u>	<u>Over-payments (percent)</u>	<u>Corporate Overpayments (Eff. 1-1-99) (percent)</u>
070174	063075	6 %	6 %	
070175	013176	9 %	9 %	
020176	013178	7 %	7 %	
020178	013180	6 %	6 %	
020180	013182	12 %	12 %	
020182	123182	20 %	20 %	
010183	063083	16 %	16 %	
070183	123184	11 %	11 %	
010185	063085	13 %	13 %	
070185	123185	11 %	11 %	
010186	063086	10 %	10 %	
070186	123186	9 %	9 %	
010187	093087	9 %	8 %	
100187	123187	10 %	9 %	
010188	033188	11 %	10 %	
040188	093088	10 %	9 %	
100188	033189	11 %	10 %	
040189	093089	12 %	11 %	
100189	033191	11 %	10 %	
040191	123191	10 %	9 %	
010192	033192	9 %	8 %	
040192	093092	8 %	7 %	

<u>Beginning Date</u>	<u>Ending Date</u>	<u>Under- payments (percent)</u>	<u>Over- payments (percent)</u>	<u>Corporate Overpay- ments (Eff. 1-1-99) (percent)</u>
100192	063094	7 %	6 %	
070194	093094	8 %	7 %	
100194	033195	9 %	8 %	
040195	063095	10 %	9 %	
070195	033196	9 %	8 %	
040196	063096	8 %	7 %	
070196	033198	9 %	8 %	
040198	123198	8%	7%	
010199	033199	7%	7%	6%
040199	033100	8%	8%	7%
040100	033101	9%	9%	8%
040101	063001	8%	8%	7%
070101	123101	7%	7%	6%
010102	123102	6%	6%	5%
010103	093003	5%	5%	4%
100103	033104	4%	4%	3%
040104	063004	5%	5%	4%
070104	093004	4%	4%	3%
100104	123104	5%	5%	4%

Dated: October 12, 2004

ROBERT C. BONNER,  
*Commissioner,  
Customs and Border Protection.*

[Published in the Federal Register, October 18, 2004 (69 FR 61401)]

DEPARTMENT OF HOMELAND SECURITY,  
OFFICE OF THE COMMISSIONER OF CUSTOMS.

*Washington, DC, October 13, 2004,*

The following documents of the Bureau of Customs and Border Protection ("CBP"), Office of Regulations and Rulings, have been determined to be of sufficient interest to the public and CBP field offices to merit publication in the CUSTOMS BULLETIN.

MICHAEL T. SCHMITZ,  
*Assistant Commissioner,  
Office of Regulations and Rulings.*



**19 CFR PART 177**

**REVOCATION OF RULING LETTER AND TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF AN AIR BLOW GUN KIT**

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of revocation of a ruling letter and revocation of treatment relating to the classification of an air blow gun kit.

SUMMARY: Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. 1625(c)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057), this notice advises interested parties that U.S. Customs and Border Protection (CBP) is revoking one ruling letter relating to the tariff classification, under the Harmonized Tariff Schedule of the United States (HTSUS), of certain metal couplings and connectors. Similarly, CBP is revoking any treatment previously accorded by it to substantially identical transactions. Notice of the proposed revocation was published on September 1, 2004, in Volume 38, Number 36 of the CUSTOMS BULLETIN. No comments were received in response to this notice.

EFFECTIVE DATE: Merchandise entered or withdrawn from warehouse for consumption on or after December 26, 2004.

FOR FURTHER INFORMATION CONTACT: David Salkeld, General Classification Branch, at (202) 572-8781.

## SUPPLEMENTARY INFORMATION:

**BACKGROUND**

On December 8, 1993, Title VI (Customs Modernization), of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057) (hereinafter "Title VI"), became effective. Title VI amended many sections of the Tariff Act of 1930, as amended, and related laws. Two new concepts which emerge from the law are **informed compliance** and **shared responsibility**. These concepts are premised on the idea that in order to maximize voluntary compliance with Customs laws and regulations, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the law imposes a greater obligation on Customs to provide the public with improved information concerning the trade community's responsibilities and rights under the Customs and related laws. In addition, both the trade and Customs share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and provide any other information necessary to enable Customs to properly assess duties, collect accurate statistics and determine whether any other applicable legal requirement is met.

Pursuant to CBP obligations, a notice was published in the September 1, 2004, CUSTOMS BULLETIN, Volume 38, Number 36, proposing to revoke New York Ruling Letter (NY) K85017, dated April 26, 2004, and to revoke any treatment previously accorded by CBP to substantially identical transactions. No comments were received in response to this notice.

In NY K85017, CBP classified an air blow gun kit under subheading 8467.19.5090, HTSUSA, which provides for "Tools for working in the hand, pneumatic, hydraulic or with self-contained electric or nonelectric motor, and parts thereof: Pneumatic: Other: Other: Other." It is now CBP's position, that the air blow gun kit subject to this notice is classified under subheading 8424.20.9000, which provides for, "Mechanical appliances (whether or not hand operated) for projecting, dispersing or spraying liquids or powders; fire extinguishers, whether or not charged; spray guns and similar appliances; steam or sand blasting machines and similar jet projecting machines; parts thereof: Spray guns and similar appliances: Other."

As stated in the proposed notice, while CBP is specifically referring to one ruling, NY K85017, this notice covers any rulings on this merchandise that may exist but have not been specifically identified. CBP has undertaken reasonable efforts to search existing data bases for rulings in addition to the one identified. No further rulings have been found. Any party who has received an interpretive ruling or decision (i.e., ruling letter, internal advice memorandum or decision, or

protest review decision) on the merchandise subject to this notice should have advised CBP during the notice period.

Similarly, pursuant to section 625(c)(2), Tariff Act of 1930 (19 U.S.C. 1625 (c)(2)), as amended by section 623 of Title VI, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. This treatment may, among other reasons, be the result of the importer's reliance on a ruling issued to a third party, CBP personnel applying a ruling of a third party to importations of the same or similar merchandise, or the importer's or CBP's previous interpretation of the HTSUS. Any person involved with substantially identical transactions should have advised CBP during the notice period. An importer's failure to advise CBP of substantially identical transactions or of a specific ruling not identified in this notice, may raise issues of reasonable care on the part of the importer or its agents for importations of merchandise subsequent to the effective date of this notice.

Pursuant to 19 U.S.C. 1625(c)(1), CBP is revoking NY K85017 and any other ruling not specifically identified that is contrary to the determination set forth in this notice to reflect the proper classification of the merchandise pursuant to the analysis set forth in Headquarters Ruling Letter (HQ) 967219 (Attachment). Additionally, pursuant to 19 U.S.C. 1625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions that is contrary to the determination set forth in this notice.

In accordance with 19 USC 1625(c), this ruling will become effective sixty (60) days after publication in the CUSTOMS BULLETIN.

DATED: October 13, 2004

John Elkins for MYLES B. HARMON,  
*Director;*  
*Commercial Rulings Division.*

Attachment

DEPARTMENT OF HOMELAND SECURITY.  
BUREAU OF CUSTOMS AND BORDER PROTECTION,

**HQ 967219**  
October 13, 2004  
**CLA-2 RR:CR:GC 967219 DSS**  
**CATEGORY:** Classification  
**TARIFF NO.:** 8424.20.9000

MS. SARALEE ANTRIM-SAZAN  
CARMICHAEL INTERNATIONAL SERVICE  
533 Glendale Boulevard  
Los Angeles, CA 90026-5097

**RE:** Revocation of NY K85017; air blow gun kit from China

DEAR MS. ANTRIM-SAZAN:

This letter is pursuant to the Bureau of Customs and Border Protection (CBP) reconsideration of New York Ruling Letter (NY) K85017, dated April 26, 2004, which was issued to you on behalf of Alltrade, Inc. by the Director, National Commodity Specialist Division, New York, with respect to the classification under the Harmonized Tariff Schedule of the United States Annotated (HTSUSA), of the air blow gun kit. After review of NY K85017, CBP has determined that the classification of the kit under subheading 8467.19.5090, HTSUS, was incorrect.

Pursuant to section 625 (c), Tariff Act of 1930 (19 USC 1625(c)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act, Pub. L. 103-182, 107 Stat. 2057, 2186 (1993), notice of the proposed revocation of NY K85017 was published in the September 1, 2004, CUSTOMS BULLETIN, Volume 38, Number 36. No comments were received in response to this notice.

**FACTS:**

In NY K85017, CBP wrote, in relevant part:

A sample has been provided of the Trades Pro 15 pc. Air Tool Accessory Kit, Model # 835048. This air blow gun kit includes a blow gun, three nozzles, two male and two female connectors, two universal adapters, two quick couplers, a dual tire chuck, tire gauge and wire brush. All of these items are packaged for retail on a hanging blister card. The blow gun (for blowing out tubes and pipes, and other air cleaning applications) will be used with a compressor. It is connected to the compressor's hose utilizing the connectors, couplers and adapters in the kit. . . .

The air blow gun kit consists of at least two different articles that are, prima facie, classifiable in different headings. The kits consist of articles put up together to carry out a specific activity (i.e., air cleaning operations). Finally, the articles are put up in a manner suitable for sale directly to users without repacking. Therefore, the kits in question are within the term "goods put up in sets for retail sale." GRI 3(b) states in part that goods put up in sets for retail sale, which cannot be classified by reference to GRI 3(a), are to be classified as if they consisted of the component which gives them their essential character. It is the opinion of this office that the air blow gun imparts the essential character to this kit.

The kit was classified under subheading 8467.19.5090, HTSUS, which provides for, "Tools for working in the hand, pneumatic, hydraulic or with self-contained electric or nonelectric motor, and parts thereof: Pneumatic: Other: Other: Other."

**ISSUE:**

What is the proper tariff classification for the instant air blow gun kit?

**LAW AND ANALYSIS:**

Classification under the HTSUSA is made in accordance with the General Rules of Interpretation (GRIs). GRI 1 provides that the classification of goods shall be determined according to the terms of the headings of the tariff schedule and any relative section or chapter notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied. GRI 2 is not applicable here except insofar as it provides that "[t]he classification of goods consisting of more than one material or substance shall be according to the principles of rule 3." GRI 3 provides as follows:

When, by application of rule 2(b) or for any other reason, goods are, *prima facie*, classifiable under two or more headings, classification shall be effected as follows:

- (a) The heading which provides the most specific description shall be preferred to headings providing a more general description. However, when two or more headings each refer to part only of the materials or substances contained in mixed or composite goods or to part only of the items in a set put up for retail sale, those headings are to be regarded as equally specific in relation to those goods, even if one of them gives a more complete or precise description of the goods.
- (b) Mixtures, composite goods consisting of different materials or made up of different components, and goods put up in sets for retail sale, which cannot be classified by reference to 3(a), shall be classified as if they consisted of the material or component which gives them their essential character, insofar as this criterion is applicable.
- (c) When goods cannot be classified by reference to 3(a) or 3(b), they shall be classified under the heading which occurs last in numerical order among those which equally merit consideration.

The Harmonized Commodity Description and Coding System Explanatory Notes (ENs) constitute the official interpretation of the Harmonized System at the international level. While not legally binding, the ENs provide a commentary on the scope of each heading of the HTSUSA and are thus useful in ascertaining the classification of merchandise under the System. CBP believes the ENs should always be consulted. *See* T.D. 89-90, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The HTSUSA provisions under consideration are as follows:

8424 Mechanical appliances (whether or not hand operated) for projecting, dispersing or spraying liquids or powders; fire extinguishers, whether or not charged; spray guns and similar appliances; steam or sand blasting machines and similar jet projecting machines; parts thereof:

8424.20	Spray guns and similar appliances:
8424.20.9000	Other
	* * * *
8467	Tools for working in the hand, pneumatic, hydraulic or with self-contained electric or nonelectric motor, and parts thereof:
	Pneumatic:
8467.19	Other:
8467.19.50	Other
8467.19.5090	Other

We still believe that the kit is considered a set under GRI 3(b) and that its essential character is provided by the air blow gun. However, upon reexamination of the kit, it is apparent that the kit is not classified under heading 8467, but instead should be classified under heading 8424, which provides for spray guns and similar appliances, by operation of Note 2 to Chapter 84, HTSUS.

The kit meets the GRI 3(b) and attendant EN (X) definition of "goods put up in sets for retail sale." First, the kit consists of at least two different articles which are, prima facie, classifiable in two different headings. Second, the items are put up together to carry out the specific activity of spraying air or air cleaning operations and the items will be used together or in conjunction with one another. Third, the articles are put up in a manner suitable for sale directly to users without repacking. We thus believe that the kit qualifies as a set of GRI 3(b).

The factor which determines essential character may be determined by the nature of the material or component, its bulk, quantity, weight or value, or by the role of a constituent material in relation to the use of the goods. GRI 3(b) EN (VIII). As was stated in NY K86865, it is the air blow gun that imparts the essential character of the kit as it sprays the air needed for the air cleaning operations.

Chapter 84, Note 2, HTSUS, states:

Subject to operation of note 3 to section XVI, a machine or appliance which answers to a description in one or more of the headings 8401 to 8424 and at the same time to a description in one or more of the headings 8425 to 8480 is to be classified under the appropriate heading of the former group and not the latter . . .

The question then is whether the air blow gun kit is classified under heading 8424, HTSUS. We believe that it is. EN 84.24 provides in pertinent part:

(B) Spray Guns and Similar Appliances

Spray guns and similar hand controlled appliances are usually designed for attaching to compressed air or steam lines, and are also connected, either directly or through a conduit, with a reservoir of the material to be projected. . . . They may also be used for projecting a powerful jet of compressed air or steam for cleaning stonework in buildings, statuary, etc.

The group also includes separately presented hand controlled “anti-smudge” spraying devices for fitting to printing machines, and hand controlled metal spraying pistols operating either on the principle of a blow pipe, or by the combined effect of an electric heating device and a jet of compressed air. . . .

The instant air gun would seem to fall under the terms of the heading and the language within EN 84.24, which states that hand controlled appliances fitted with triggers or other valves for controlling flow through the nozzle fall under heading 8424. Furthermore, similar products have been classified under subheading 8424.20.90, HTSUS. In NY 832130, dated October 14, 1988, CBP classified an air blow gun used for cleaning dust and other impurities, and a general purpose spray gun used for high volume application of enamels, varnish and similar materials under that heading. *See also* NY R00091, dated February 5, 2004 (classifying spray-on tanning system under subheading 8424.20); NY F80605, dated December 16, 1999; NY 801566, dated September 14, 1994; and NY 865507, dated August 15, 1991.

From the description provided to CBP, we feel that the air blow gun falls under the definition of spray gun or similar appliance for tariff purposes. In this instance, the air blow gun will be connected to a compressor and will be used to blow out tubes and pipes and for other air-cleaning operations by shooting a jet of compressed air. Chapter 84, Note 2 compels classification of this kit under heading 8424.

**HOLDING:**

In accordance with the above discussion, the correct classification for the air blow gun kit is under subheading 8424.20.9000, HTSUSA, which provides for “Mechanical appliances (whether or not hand operated) for projecting, dispersing or spraying liquids or powders; fire extinguishers, whether or not charged; spray guns and similar appliances; steam or sand blasting machines and similar jet projecting machines; parts thereof: Spray guns and similar appliances: Other.” The 2004 general rate of duty is free.

Duty rates are provided for your convenience and are subject to change. The text of the most recent HTSUS and the accompanying duty rates are provided on the World Wide Web at [www.usitc.gov](http://www.usitc.gov).

**EFFECT ON OTHER RULINGS:**

NY K85017 is REVOKED. In accordance with 19 U.S.C. 1625(c), this ruling will become effective 60 days after its publication in the CUSTOMS BULLETIN.

John Elkins for MYLES B. HARMON,  
*Director,*  
*Commercial Rulings Division.*

**PROPOSED MODIFICATION OF RULING LETTER AND TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF HOMEOPATHIC PRODUCTS**

**AGENCY:** Bureau of Customs and Border Protection, Department of Homeland Security

**ACTION:** Notice of proposed modification of a tariff classification ruling letter and treatment relating to the classification of homeopathic products.

**SUMMARY:** Pursuant to section 625(c), Tariff Act of 1930 (19 U.S.C. 1625 (c)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057), this notice advises interested parties that Customs intends to revoke two rulings concerning the tariff classification of homeopathic products, under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, Customs intends to revoke any treatment previously accorded by Customs to substantially identical transactions. Comments are invited on the correctness of the proposed actions.

**DATE:** Comments must be received on or before November 26, 2004.

**ADDRESS:** Written comments are to be addressed to Bureau of Customs and Border Protection, Office of Regulation and Rulings, Attention: Regulations Branch, 1300 Pennsylvania Avenue, N.W., Washington, D.C. 20229. Comments submitted may be inspected at 799 9<sup>th</sup> St. N.W. during regular business hours. Arrangements to inspect submitted comments should be made in advance by calling Joseph Clark at (202) 572-8768.

**FOR FURTHER INFORMATION CONTACT:** Allyson Mattanah, General Classification Branch, (202) 572-8784.

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 8, 1993, Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057) (hereinafter "Title VI"), became effective. Title VI amended many sections of the Tariff Act of 1930, as amended, and related laws. Two new concepts which emerge from the law are "informed compliance" and "shared responsibility." These concepts are premised on the idea that in order to maximize voluntary compliance with Customs laws and regulations, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the law imposes a greater obligation on Customs to provide the public with improved information concerning

the trade community's responsibilities and rights under the Customs and related laws. In addition, both the trade and Customs share responsibility in carrying out import requirements. For example, under section 484 of the Tariff Act of 1930, as amended (19 U.S.C. § 1484), the importer of record is responsible for using reasonable care to enter, classify and value imported merchandise, and provide any other information necessary to enable Customs to properly assess duties, collect accurate statistics and determine whether any other applicable legal requirement is met.

Pursuant to section 625(c)(1), Tariff Act of 1930 (19 U.S.C. 1625(c)(1)), as amended by section 623 of Title VI (Customs Modernization) of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057), this notice advises interested parties that Customs intends to revoke two rulings pertaining to the tariff classification of homeopathic products.

Although in this notice Customs is specifically referring to Headquarters Ruling Letters (HQ) 964882, dated September 26, 2002, and 964188, dated April 3, 2002, this notice covers any rulings on this merchandise which may exist but have not been specifically identified. Customs has undertaken reasonable efforts to search existing data bases for rulings in addition to those identified. No further rulings have been found. This notice will cover any rulings on this merchandise that may exist but have not been specifically identified. Any party who has received an interpretive ruling or decision (i.e., ruling letter, internal advice memorandum or decision or protest review decision) on the merchandise subject to this notice should advise Customs during this notice period.

Similarly, pursuant to section 625(c)(2), Tariff Act of 1930 (19 U.S.C. 1625(c)(2)), as amended by section 623 of Title VI, Customs intends to revoke any treatment previously accorded by Customs to substantially identical transactions. This treatment may, among other reasons, be the result of the importer's reliance on a ruling issued to a third party, Customs personnel applying a ruling of a third party to importations of the same or similar merchandise, or the importer's or Customs previous interpretation of the Harmonized Tariff Schedule of the United States (HTSUS). Any person involved in substantially identical transactions should advise Customs during this notice period. An importer's failure to advise Customs of substantially identical transactions or of a specific ruling not identified in this notice may raise issues of reasonable care on the part of the importer or his agents for importations of merchandise subsequent to this notice.

In HQ 964882 we stated that homeopathic products that do not contain a significantly detectable amount of the claimed active ingredient should not be classified in chapter 30, HTSUS, as medicaments. However, upon further consideration, we no longer are of the view that the relevant standard in classifying homeopathic products

is our ability to detect the presence of the active ingredient. Homeopathic products are considered to be drugs by the FDA. They all must comply with the standards listed in the HPUS. They all must be packaged with statements of the specific diseases, ailments or their symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the recommended dosage and the mode of application. They are all marketed and sold in relation to a disease, condition, or ailment which they purport to treat. If the condition is a very serious one, e.g. cancer, they are sold only by prescription. Hence, we find that in the context of homeopathic products, the outcome of the principal use test should not be based on the degree of dilution of the active ingredient in the homeopathic product. Therefore, we no longer believe that classifying homeopathic products according to the dilution of the active ingredient is correct.

Customs, pursuant to 19 U.S.C. 1625(c)(1), intends to revoke HQs 964882 and 964188, set forth as Attachments "A" and "B" respectively, and any other ruling not specifically identified, to reflect the proper classification of the merchandise pursuant to the analysis in proposed HQs 967075 and 967363, set forth respectively as Attachments "C" and "D" to this document. Additionally, pursuant to 19 U.S.C. 1625(c)(2), Customs intends to revoke any treatment previously accorded by Customs to substantially identical transactions. Before taking this action, consideration will be given to any written comments timely received.

Dated: October 13, 2004

MYLES B. HARMON,  
*Director,*  
*Commercial Rulings Division.*

Attachments

[ATTACHMENT A]

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,  
HQ 964882  
September 26, 2002  
CLA-2 RR:CR:GC 964882ptl  
CATEGORY: Classification  
TARIFF NO.: 2106.90.9998

PORT DIRECTOR  
U.S. CUSTOMS SERVICE  
11099 S. La Cienega Blvd.  
Los Angeles, CA 90045

RE: Protest 2720-00-100769; Homeopathic Products

DEAR PORT DIRECTOR:

The following is our decision on Protest 2720-00-100769, filed by counsel on behalf of Boiron USA, against your classification of various homeopathic liquid and tablet preparations under the Harmonized Tariff Schedule of the United States (HTSUS).

**FACTS:**

The 45 entries covering merchandise that are the subject of this protest were made between May 26, 1999 and May 30, 2000. In these entries, the various products at issue, identified as homeopathic medicines by Boiron, were classified as medicaments in heading 3004, HTSUS. Samples of the products were sent to Customs Laboratories for analysis. Based upon the results of these tests, the goods were reclassified by Customs in subheading 2106.90.9998, HTSUS, which provides for food preparations not elsewhere specified or included, . . . other. The entries liquidated between July 28, 2000 and September 22, 2000.

On November 8, 2000, counsel filed a protest with Customs in which it argued that the original classification provided by Boiron was correct and the entries should be reliquidated as entered.

In preparing this decision, consideration has been given to supplemental documents provided by protestant in April and May 2002, as well as information and materials presented to members of my staff during a teleconference on May 22, 2002.

**ISSUE:**

What is the classification of the Boiron homeopathic products?

**LAW AND ANALYSIS:**

Initially we note that the protest (Customs Form 19) was received by Customs on November 8, 2000. Using the November 8, 2000, date as the date of filing of the protest, as to the entries liquidated on July 28, 2000, (see Attachment "A"), the protest was untimely filed *i.e.*, a protest must be filed within 90 days after but not before the notice of liquidation (19 U.S.C. § 1514(c)(3)(A); 19 C.F.R. § 174.12(e)); the notices of liquidation were dated July 28, 2000, and the protest was filed November 8, 2000, 102 days [3 days in July, 31 in August, 30 in September, 30 in October, and 8 in November equals 102 days] after the notice of liquidation). For an example of the judicial treatment of a protest filed after the 90-day period for filing a protest, see *Penrod Drilling Co. v. United States*, 13 CIT 1005, 727 F. Supp. 1463, *re-*

*hearing dismissed*, 14 CIT 281, 740 F. Supp. 858 (1990), *affirmed*, 9 Fed. Cir. (T) 60, 925 F. 2d 406 (1991). The protest must be denied as to the entries liquidated on July 28, 2000. As to the remaining entries (see Attachment "B"), the protest was timely filed (see above) and the matter protested is protestable (see 19 U.S.C. § 1514(a)(2) and (5)).

Merchandise is classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) in accordance with the General Rules of Interpretation (GRIs). The systematic detail of the HTSUS is such that virtually all goods are classified by application of GRI 1, that is, according to the terms of the headings of the tariff schedule and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied in order.

In understanding the language of the HTSUS, the Harmonized Commodity Description and Coding System Explanatory Notes may be utilized. The Explanatory Notes (ENs), although not dispositive or legally binding, provide a commentary on the scope of each heading of the HTSUS, and are the official interpretation of the Harmonized System at the international level. See T.D. 89-80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The HTSUS provisions under consideration are as follows:

<b>2106</b>	Food preparations not elsewhere specified or included
2106.90	Other:
	Other
	Other
	Other
	Other
2106.90.99	Other
<b>3004</b>	Medicaments (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:
	*    *    *
3004.90	Other:
3004.90.90	Other
3004.90.9090	Other

We note that In the protest filed, protestant begins by stating that: 'the imported homeopathic medicines were reclassified by Customs in either HTS, subheading 1702.19.00.00 [sic] as lactose (in the case of tablets) or under HTS, subheading 2208.90.75.00 [sic] as an alcoholic beverage (in the case of liquid homeopathic medicines).' Then, on the next page of the protest, counsel states: "The Notice of Action reclassified items 3004.90.9090 and 3003.90.0000 (medicaments), which are not subject to any duty, to 2106.90.9998 (food preparations), levying duties of 6.4% for 2000 entries and 7% for 1999 entries." As point of fact, Customs liquidated all entries in sub-

heading 2106.90.9998, HTSUS, as food preparations, not elsewhere specified.

Protestant asserts that because its homeopathic products are marketed and distributed to treat specific “ailments” and “conditions”, they should be classified as medicaments in heading 3003 or 3004, HTSUS.

To be classified in headings 3003 and 3004, HTSUS, a product must be used in the internal or external treatment (therapeutic use) or prevention (prophylactic use) of human or animal ailments. EN 30.04(a) requires that products put up in measured doses should be used for the direct treatment of certain diseases. Paragraph (b) requires that there be a statement of the disease or condition which the product is intended to cure or relieve. This paragraph also advises that the mere indication of pharmaceutical or other degree of purity is not alone sufficient to justify classification in that heading.

The ENs covering medicaments need to be read in conjunction with each other. EN (1) to heading 30.03 states that the heading includes “mixed medicinal preparations such as those listed in an official pharmacopoeia.” But the products must contain active ingredients at sufficiently high levels to be regarded as having primarily therapeutic or prophylactic effects. The EN continues: “ However, this should not be taken to mean that preparations listed in an official pharmacopoeia, proprietary medicines, etc. are always classified in heading 30.03. For example, anti-acne preparations which are designed primarily to cleanse the skin and which do not contain sufficiently high levels of active ingredients to be regarded as having a primary therapeutic or prophylactic effect against acne are to be classified in heading 33.04.” This concept is repeated in the EN to heading 3004 where it states that “throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.” (Emphasis added)

Although no clear criteria is provided in either the tariff text or the ENs to differentiate products which are medicinal preparations from those which are designed to maintain general health and well-being, there is a definite distinction made between them. The only exact criterion provided is in Chapter 17, Additional U.S. note 11, which provides that : “ ‘cough drops’ must contain a minimum of 5 mg per dose of menthol, of eucalyptol, or a combination of menthol and eucalyptol.” This U.S. note is based on a Food and Drug Administration (FDA) opinion that a 5 mg or larger dose of menthol is therapeutic. This treatment is supported by language of EN 30.04 which provides, in relevant part, as follows:

“However, preparations put up as throat pastilles or cough drops, consisting essentially of sugars (whether or not with other foodstuffs such as gelatin, starch or flour) and flavouring agents (including substances having medicinal properties, such as benzyl alcohol, menthol, eucalyptol and tolu balsam) fall in heading 17.04. Throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.”

Protestant concedes that its products are not intended to be used for prophylactic purposes, but contends that because they are marketed as homeopathic products, they are used by persons for therapeutic purposes and should therefore be classified as medicaments in heading 3004, HTSUS.

According to the internet web page of the Homeopathic Pharmacopoeia of the United States, "Homeopathy is the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people." The particularized remedy is designed to address the symptoms exhibited by the afflicted patient. Further, "Any substance may be considered a homeopathic medicine if it has known 'homeopathic provings' and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States."

One of the principal concepts of Homeopathy is the "Law of Infinitesimals." This principal holds that the smaller the dose of the substance, the more powerful will be its healing effects. Potentization, or dynamization, is the sequential dilution of a substance to release its immaterial and spiritual powers. The process is called attenuation when it refers to liquids and trituration when it refers to solid preparations. For example, the starting substance is first mixed in alcohol to obtain a tincture. One drop of the tincture is mixed with 99 drops of alcohol (to achieve a ration of 1:100) and the mixture is strongly shaken. This shaking process is known as succussion. This bottle is labeled as "1C" or "2X." One drop of this 1C is then mixed with 100 drops of alcohol and the process is repeated to make 2C. By the time 3C (6X) is reached, the dilution is 1 part in 1 million. These preparations are referred to as submolecular. It is the contention of protestant that it is the overall preparation, and not any particular element of it, that is the "active" component of a homeopathic drug.

Basic laws of chemistry place a limit on the dilutions that can be made without losing the original substance altogether. Once this limit, called Avogadro's Number ( $6.023 \times 10^{23}$  — the number of molecules in 1 mole of substance) is reached, the original substance is totally undetectable. The sequential dilutions used to prepare homeopathic preparations create products in which the "active" ingredients are virtually undetectable. Current scientific instruments can detect compounds which have been diluted to the 16X/8C level.

Customs has been consistent in its treatment between products which contain "sufficient" or "efficacious" levels of active ingredients for medical purposes and those which have only low levels of active ingredients. See HQ 957394, dated February 5, 1998, on Fisherman's Friend mentholated lozenges, HQ 961061, dated August 24, 1998, on Hall's Sugar Free Cough Drops, HQ 958150, dated April 7, 1998, on Hall's Vitamin C Drops, HQ 963764, dated January 11, 2002, on Certs Mints, and HQ 964188, dated April 3, 2002, and HQ 964494, dated August 28, 2002, on homeopathic products.

To support the proposition that the products should be classified in heading 3004, HTSUS, protestant points out that according to the definitions contained in section 321(g)(1) of the Food, Drug and Cosmetic Act (FDCA) (21 USC 301 et seq.), the term "drug" includes "articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia, or official National Formulary, or any supplement to them; . . . ." Protestant

also points out that this definition requires the U.S. Food and Drug Administration (FDA) to oversee homeopathic products. This oversight is accomplished by means of regulations and Compliance Policy Guides issued by the FDA which govern the labeling and marketing of homeopathic products. However, under this regulatory scheme, much greater leeway is accorded homeopathic products than mainstream drugs. Among some of the more significant differences is that homeopathic drug manufacturers are exempt from expiration dating their products, and laboratory determination of the identity and strength of each active ingredient. Additionally, homeopathic drug manufacturers are exempt from the requirements that they register a new product for an Investigational New Drug (IND) number at early stages of development and they are not required to submit new drug applications, nor do they have to prove the safety and efficacy of their products before marketing them.

We have previously noted that the introduction to the Homeopathic Pharmacopoeia of the United States provides, in part, that “[a]ny substance may be considered a homeopathic medicine . . . [if it] is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States (HPUS).” Since the FDA is required by law to accept as drugs articles claimed by their manufacturers to be homeopathic products because they are included HPUS, essentially any substance can, through this process, be considered a drug.

While we recognize the treatment which the FDA law requires that agency to accord protestant’s products, Customs does not believe that products which do not contain sufficient active medicinal ingredients satisfy the tariff requirements for classification as medicaments. We note that it is a long established principle of Customs practice that the characterization of imported merchandise by governmental agencies for other than tariff purposes does not determine tariff classification. See *United States v. Mercantil Distribuidora et al.*, 45 C.C.P.A. (Customs) 20, C.A.D. 667 (1957); *Marine Products Co. v. United States*, 42 Cust. Ct. 154 (C.D. 2080) (1959). We also note that the courts have also held that inclusion in the United States Pharmacopoeia or National Formulary does not automatically establish that classification [by the FDA] of such article as a “drug” is reasonable. *National Nutritional Foods Ass’n. v. Matthews*, 557 F.2d 325 (1977).

Protestant has referred to several New York rulings dating from 1994, which classified some homeopathic products in heading 3004, HTSUS, and states that these rulings should be a basis for similar treatment of his product. Unfortunately, none of the rulings cited by protestant provide a detailed composition for any of the products classified and all records relating to those rulings have been lost as a result of the destruction of the Customs offices at the World Trade Center in New York on September 11, 2001. We note that the language of the ENs 3003 states that although components of a product are listed in an official pharmacopoeia that “this should not be taken to mean that preparations listed in an official pharmacopoeia, proprietary medicines, etc. are always classified in heading 30.03 [and, by extension heading 3004].” Since we do not have full details of those rulings, we will not base classification of protestant’s products on an incomplete record.

While they are not treated as dispositive, decisions of the Harmonized Systems Committee (HSC) of the World Customs Organization can provide guidance in the interpretation of tariff construction. Over several years, the HSC considered the classification of products identified as “Bach Flower”

preparations and "Original Schwedenbitter." In 1994, in Annex G/4 to Doc 38.960, the HSC determined that the Bach Flower remedies were not classifiable in heading 3004 since no active therapeutic or prophylactic ingredients had been detected by the various Customs Laboratories. Similarly, the Schwedenbitter was not classifiable in heading 3004 because the product was not a medicament. Because of their substantial ethanol content, the HSC decided to classify both products in heading 2208.

Based on the above analysis and discussion of the language of the HTSUS, the ENs and relevant Customs rulings, we are of the opinion that even though homeopathic products are marketed and labeled in a manner approved by the FDA indicating that they are intended to be used by purchasers for therapeutic purposes that unless such products contain a significantly detectable amount of that particular element or compound that is claimed to be an "active ingredient," such products are similar to placebos and should not be classified in chapter 30, HTSUS, as medicaments. We have determined that products which contain dilutions of active ingredients less than or equal to 16X or 8C may be classified in chapter 30, HTSUS, provided that Customs is able to detect significant levels of the "active ingredient." While we realize the homeopath contends that the entire dilution or succintion is the "active ingredient," for classification purposes, "active ingredient" will be taken to mean that herb or element identified on the label as the item which supposedly distinguishes one product from another similarly diluted product. If the identifying component can be detected in quantities that can be considered effective, and that component is included in the HPUS, and the product is labeled in accordance with FDA guidelines, then Customs will concede classification in heading 3004, HTSUS.

Customs has taken samples of over 50 of the products which are under protest. In no instance, do the results of the laboratory analysis indicate that any of the products contain detectable amounts of active ingredients, let alone quantities which can be considered sufficient for therapeutic or prophylactic purposes of chapter 30.

Since the subject merchandise is precluded from classification in chapter 30, classification must be based on the detectable components of the products. The products are in the form of edible articles for human consumption (tablets, liquids and syrups). Accordingly, they are classified in heading 2106, HTSUS, as food products not elsewhere specified or included.

**HOLDING:**

Accordingly, based on the above discussion the homeopathic products which are the subject of this protest do not contain significant detectable amounts of active ingredients which have therapeutic or prophylactic uses. Because they are intended to be consumed by humans, they are classified in subheading 2106.90.9998, HTSUS, which provides for food preparations not elsewhere specified or included, other, . . . other.

The protest should be DENIED. In accordance with Section 3A(11)(b) of Customs Directive 099 3550 065, dated August 4, 1993, Subject: Revised Protest Directive, you are to mail this decision, together with the Customs Form 19, to the protestant no later than 60 days from the date of this letter. Any reliquidation of the entry or entries in accordance with the decision must be accomplished prior to mailing the decision.

Sixty days from the date of the decision, the Office of Regulations and Rulings will make the decision available to Customs personnel, and to the pub-

lic on the Customs Home Page on the World Wide Web at [www.customs.gov](http://www.customs.gov), by means of the Freedom of Information Act, and other methods of public distribution.

Marvin Amernick for MYLES B. HARMON,  
*Acting Director,*  
*Commercial Rulings Division.*



ATTACHMENT A

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,

Entries Liquidated on July 28, 2000:

112-xxxx2612  
112-xxxx6678  
112-xxxx4666  
112-xxxx5450  
112-xxxx7546  
112-xxxx1060  
112-xxxx9435  
112-xxxx7571  
112-xxxx0598  
112-xxxx6436  
112-xxxx7742  
112-xxxx9043  
112-xxxx7105  
112-xxxx0282  
112-xxxx7920  
112-xxxx8488  
112-xxxx0474  
112-xxxx1734  
112-xxxx0231  
112-xxxx8394  
112-xxxx0138  
112-xxxx6436  
112-xxxx9068  
112-xxxx5500  
112-xxxx5471  
112-xxxx0197  
112-xxxx9876  
112-xxxx3079

ATTACHMENT B

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,

Entries Liquidated on August 11, 2000:

112-xxxx2642  
112-xxxx1406

Entries Liquidated on August 25, 2000:

112-xxxx9209  
112-xxxx0811  
112-xxxx0329  
112-xxxx0843  
112-xxxx5337  
112-xxxx4783  
112-xxxx6121  
112-xxxx5611  
112-xxxx8916  
112-xxxx1506

Entry Liquidated September 1, 2000:

112-xxxx0380

Entry Liquidated September 8, 2000:

112-xxxx2469

Entries Liquidated September 15, 2000:

112-xxxx1927 112-xxxx4468

Entry Liquidated September 22, 2000:

112-xxxx0640



[ATTACHMENT B]

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,

HQ 964188  
April 3, 2002  
CLA-2 RR:CR:GC 964188ptl  
CATEGORY: Classification  
TARIFF NO.: 2106.90.9998

PORT DIRECTOR  
U.S. CUSTOMS SERVICE  
*11099 S. La Cienega Blvd.  
Los Angeles, CA 90045*

RE: Protest 2720-00-100187, "Drink Ease" and "No Jet Lag" Homeopathic Products

DEAR PORT DIRECTOR:

The following is our decision on Protest 2720-00-100187, filed by counsel on behalf of Global Source, against your classification of products identified

as “Drink Ease” and “No Jet Lag” under the Harmonized Tariff Schedule of the United States (HTSUS).

**FACTS:**

According to information supplied by protestant, “Drink Ease” and “No Jet Lag” are marketed as homeopathic drugs. Each of the products is packaged for retail sale with 30 tablets in a safety sealed blister strip. The outer package is labeled in accordance with regulations of the Food and Drug Administration (FDA) with active ingredient names and potencies, indications, warnings and dosage information. Both products are compressed tablets made of sorbitol (a non-nutritive sweetening agent commonly used to make tablets), sterilized talc and magnesium stearate (both are inactive ingredients used as lubricants/separators in tablet compression). Equal amounts of five homeopathic active ingredients which have been processed by the manufacturer according to rules established by the Homeopathic Pharmacopoeia of the United States are sprayed onto the tablets. The active ingredients have homeopathic potencies of “30C.” “Drink Ease” is marketed for the relief of alcoholic hangovers and contains *Avena Sativa* (oats), *Capsicum Annuum* (pepper), *Nux Vomica* (identified as nutmeg, actually strychnine), *Veratrum Album* (white hellebore) and *Zinc Metallicum* (zinc metal). “No Jet Lag” is marketed for relief of tiredness associated with air travel and contains *Arnica Montana* (leopard’s bane), *Bellis Perennis* (daisy), *Chamomilla* (wild chamomile), *Ipecacuanha* (ipecac) and *Lycopodium* (clubmoss).

The products were entered from March through November 1999, under subheading 3004.90.9090, HTSUS, which provides for: Medicaments (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: . . . other: . . . other . . . other. All protested entries were liquidated on January 28, 2000, and the products were classified in subheading 2106.90.9998, HTSUS, which provides for: Food preparations not elsewhere specified or included: other, other, other, other, other, other, other. A timely protest was filed on April 14, 2000.

**ISSUE:**

What is the classification of the homeopathic products “Drink Ease” and “No Jet Lag”?

**LAW AND ANALYSIS:**

Merchandise is classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) in accordance with the General Rules of Interpretation (GRIs). The systematic detail of the HTSUS is such that virtually all goods are classified by application of GRI 1, that is, according to the terms of the headings of the tariff schedule and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied in order.

In understanding the language of the HTSUS, the Harmonized Commodity Description and Coding System Explanatory Notes may be utilized. The Explanatory Notes (ENs), although not dispositive or legally binding, provide a commentary on the scope of each heading of the HTSUS, and are the official interpretation of the Harmonized System at the international level. See T.D. 89–80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The HTSUS provisions under consideration are as follows:

**2106** Food preparations not elsewhere specified or included

\* \* \*

2106.90 Other:

Other:

Other:

Other:

Other:

2106.90.99 Other

2106.90.9998 Other

**3004** Medicaments (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:

\* \* \*

3004.90 Other:

3004.90.90 Other

3004.90.9090 Other

Protestant asserts that because its homeopathic products, "Drink Ease" and "No Jet Lag" are marketed and distributed to treat specific "ailments" (if a hangover or jet lag can properly be considered an "ailment") they should be classified as medicaments in heading 3003 or 3004, HTSUS.

According to the internet web page of the Homeopathic Pharmacopoeia of the United States, "Homeopathy is the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people." Further, "Any substance may be considered a homeopathic medicine if it has known 'homeopathic provings' and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States."

One of the principal concepts of Homeopathy is the "Law of Infinitesimals." This principal holds that the smaller the dose of the substance, the more powerful will be its healing effects. Potentization, or dynamization, is the sequential dilution of a substance to release its immaterial and spiritual powers. The process is called attenuation when it refers to liquids and trituration when it refers to solid preparations. For example, the starting substance is first mixed in alcohol to obtain a tincture. One drop of the tincture is mixed with 99 drops of alcohol (to achieve a ration of 1:100) and the mixture is strongly shaken. This shaking process is known as succussion. The final bottle is labeled as "1C." One drop of this 1C is then mixed with 100 drops of alcohol and the process is repeated to make 2C. By the time 3C is reached, the dilution is 1 part in 1 million.

In the instant products, we have potencies of “30C” which is  $1 \times 10^{-60}$ . Basic laws of chemistry place a limit on the dilutions that can be made without losing the original substance altogether. This limit, called Avogadro’s Number ( $6.023 \times 10^{23}$  — the number of molecules in 1 mole of substance), is reached with homeopathic potencies of 12C or 24X. After that, any trace of the original substance is totally undetectable.

To be classified in headings 3003 and 3004, HTSUS, a product must be used in the internal or external treatment (therapeutic use) or prevention ((prophylactic use) of human or animal ailments. EN 30.04(a) requires that products put up in measured doses should be used for the direct treatment of certain diseases. Paragraph (b) requires that there be a statement of the disease or condition which the product is intended to cure or relieve. This paragraph also advises that the mere indication of pharmaceutical or other degree of purity is not alone sufficient to justify classification in that heading.

The ENs covering medicaments need to be read in conjunction with each other. EN (1) to heading 30.03 states that the heading includes “mixed medicinal preparations such as those listed in an official pharmacopoeia.” But the products must contain active ingredients at sufficiently high levels to be regarded as having primarily therapeutic or prophylactic effects. The EN continues: “However, this should not be taken to mean that preparations listed in an official pharmacopoeia, proprietary medicines, etc. are always classified in heading 30.03. For example, anti-acne preparations which are designed primarily to cleanse the skin and which do not contain sufficiently high levels of active ingredients to be regarded as having a primary therapeutic or prophylactic effect against acne are to be classified in heading 33.04.” This concept is repeated in the EN to heading 3004 where it states that “throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.” (Emphasis added)

Although no clear criteria is provided in either the tariff text or the ENs to differentiate products which are medicinal preparations from those which are designed to maintain general health and well-being, there is a definite distinction made between them. The only exact criterion provided in the United States is in Chapter 17, Additional U.S. note 11: “ ‘cough drops’ must contain a minimum of 5 mg per dose of menthol, of eucalyptol, or a combination of menthol and eucalyptol.” Thus U.S. note is based on FDA opinion that a 5 mg or larger dose of menthol is therapeutic. This treatment is supported by language of EN 30.04 which provides, in relevant part:

“However, preparations put up as throat pastilles or cough drops, consisting essentially of sugars (whether or not with other foodstuffs such as gelatin, starch or flour) and flavouring agents (including substances having medicinal properties, such as benzyl alcohol, menthol, eucalyptol and tolu balsam) fall in heading 17.04. Throat pastilles or cough drops containing substances having medicinal properties, other than flavouring agents, remain classified in this heading when put up in measured doses or in forms or packings for retail sale, provided that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.”

Customs has been consistent in its treatment between products which contain “sufficient” or “efficacious” levels of active ingredients for medical purposes and those which have only low levels of active ingredients. See HQ 957394, dated February 5, 1998, on Fisherman’s Friend mentholated lozenges, HQ 961061, dated August 24, 1998, on Hall’s Sugar Free Cough Drops, HQ 958150, dated April 7, 1998, on Hall’s Vitamin C Drops, and HQ 963764, dated January 11, 2002.

While they are not treated as dispositive, decisions of the Harmonized Systems Committee (HSC) of the World Customs Organization can provide guidance in the interpretation of tariff construction. Over several years, the HSC considered the classification of products identified as “Bach Flower” preparations and “Original Schwedenbitter.” In 1994, in Annex G/4 to Doc 38.960, the HSC determined that the Bach Flower remedies were not classifiable in heading 3004 since no active therapeutic or prophylactic ingredients had been detected by the various Customs Laboratories. Similarly, the Schwedenbitter was not classifiable in heading 3004 because the product was not a medicament. Because of their substantial ethanol content, the HSC decided to classify both products in heading 2208.

Protestant points out that according to the definitions contained in section 321(g)(1) of the Food, Drug and Cosmetic Act (FDCA) (21 USC 301 et seq.), the term “drug” includes “articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia, or official National Formulary, or any supplement to them; . . .” Protestant also points out that this definition requires the FDA to oversee homeopathic products. This oversight is accomplished by means of regulations and Compliance Policy Guides issued by the FDA which govern the labeling and marketing of homeopathic products. Under this regulatory scheme, much greater leeway is accorded homeopathic products than mainstream drugs. Among some of the more significant differences is that homeopathic drug manufacturers are not required to submit new drug applications, nor do they have to prove the safety and efficacy of their products before marketing them.

In spite of the treatment which the FDA law requires that agency to accord protestant’s products, Customs does not believe that either product contains sufficient active ingredient medicaments to satisfy the tariff requirements for classification as medicaments. We note that it is a long established principle of customs practice that the characterization of imported merchandise by governmental agencies for other than tariff purposes does not determine tariff classification. See *United States v. Mercantil Distribuidora et al.*, 45 C.C.P.A. (Customs) 20, C.A.D. 667 (1957); *Marine Products Co. v. United States*, 42 Cust. Ct. 154 (C.D. 2080) (1959). We also note that the courts have also held that inclusion in the United States Pharmacopoeia or National Formulary does not automatically establish that classification [by the FDA] of such article as a “drug” is reasonable. *National Nutritional Foods Ass’n. v. Matthews*, 557 F.2d 325 (1977).

Protestant has referred to several New York rulings dating from 1994, which classified homeopathic products in heading 3004, HTSUS, and states that these rulings should be a basis for similar treatment of his product. Unfortunately, none of the rulings cited by protestant provide a detailed composition for any of the products classified. All records relating to those rulings have been lost as a result of the incident in New York on September 11, 2001. We note that one of the rulings cited by protestant ( NY A82970) was revoked by HQ 963794, dated April 20, 2000, which reclassified valerian

herbal tablets from heading 3004, HTSUS, to heading 2106, HTSUS. We also note that the language of the ENs 3003 states that although components of a product are listed in an official pharmacopoeia that "this should not be taken to mean that preparations listed in an official pharmacopoeia, proprietary medicines, etc. are always classified in heading 30.03 [and, by extension heading 3004]." Since we do not have full details of those rulings, we will not base classification of protestant's products on an incomplete record.

Neither product under consideration contains an identifiable amount of a product which contains a therapeutic or prophylactic property with respect to any identifiable illness or disease. HOLDING:

Accordingly, based on the above discussion and the composition of the products, "Drink Ease" and "No Jet Lag," are classified in subheading 2106.90.9998, HTSUS, which provides for: food preparations not elsewhere specified or included: other, other, other, other, other, other, other.

The protest should be DENIED. In accordance with Section 3A(11)(b) of Customs Directive 099 3550 065, dated August 4, 1993, Subject: Revised Protest Directive, you are to mail this decision, together with the Customs Form 19, to the protestant no later than 60 days from the date of this letter. Any reliquidation of the entry or entries in accordance with the decision must be accomplished prior to mailing the decision.

Sixty days from the date of the decision, the Office of Regulations and Rulings will make the decision available to Customs personnel, and to the public on the Customs Home Page on the World Wide Web at [www.customs.gov](http://www.customs.gov), by means of the Freedom of Information Act, and other methods of public distribution.

JOHN DURANT,  
*Director,*  
*Commercial Rulings Division.*

[ATTACHMENT C]

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,  
HQ 967075  
CLA-2 RR:CR:GC 967075AM  
CATEGORY: Classification  
TARIFF NO.: 3004.90.9190

MR. DANIEL E. WALTZ  
PATTON BOGGS LLP  
2550 M Street, NW  
Washington, DC 20037-1350

RE: HQ 964882 Homeopathic Products

DEAR MR. WALTZ:

This is in reference to Headquarters Ruling Letter (HQ) HQ 964882, dated September 26, 2002, regarding the classification of various homeopathic liquid and tablet preparations, pursuant to the Harmonized Tariff

Schedule of the United States (HTSUS). We have reviewed this ruling and find it to be incorrect. Accordingly, we propose to revoke it.

**FACTS:**

HQ 964882 ruled on Protest 2720-00-100769, filed by counsel on behalf of Boiron USA. The 45 entries covering merchandise that are the subject of this protest were made between May 26, 1999 and May 30, 2000. In these entries, the various products at issue, identified as homeopathic medicines by Boiron, were classified as medicaments in heading 3004, HTSUS.

The Federal Food Drug and Cosmetic Act ("FFDCA") (21 U.S.C. §§ 301 *et seq.*), states, in pertinent part, that "the term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) (21 U.S.C. § 321(g)(1)).

In 1988, FDA issued a compliance policy guide ("CPG"), entitled "Conditions under Which Homeopathic Drugs May be Marketed" (Sec. 400.400 CPG 7132.25), describing FDA's regulatory approach toward homeopathic medicines. The CPG explains that Homeopathic products must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopoeia (21 U.S.C. 351). Additionally, product labeling must comply with the labeling provisions of Sections 502 and 503 of the FFDCA and Part 201 (21 CFR 201). Each product must bear the name and place of business of the manufacturer, adequate directions for use, a statement of the quantity and amount of ingredients in the product expressed in homeopathic terms, indications for use, and warnings as described in 21 CFR 201 *et seq.* The CPG explains that homeopathic products are subject to FDA enforcement if they are misbranded, or violate any FDA adulteration or promotional restrictions. Furthermore, Section 503(b) of the FFDCA mandates that homeopathic products offered for conditions not amenable to over-the-counter use must be marketed as prescription products. Lastly, the FDA does not regulate these products under the Dietary Supplement Health and Education Act of 1994, (21 U.S.C. 301 *et seq.*), which amended the FFDCA by adding provisions to regulate dietary supplements as it does food.

Samples of the merchandise show that the outer package is labeled in accordance with regulations of the FFDCA as a homeopathic drug, with active ingredient names and potencies, indications, warnings and dosage information. Furthermore, the active ingredients have been processed in accordance with the Homeopathic Pharmacopoeia of the United States (HPUS).

These samples were sent to CBP Office of Laboratories and Scientific Services for analysis. Based upon the results of these tests, the goods were reclassified by CBP in subheading 2106.90.9998, HTSUS, which provides for food preparations not elsewhere specified or included, . . . other. The entries liquidated between July 28, 2000 and September 22, 2000. On November 8, 2000, counsel filed a protest with CBP in which it argued that the original classification provided by Boiron was correct and the entries should be reliquidated as entered.

**ISSUE:**

What is the classification of homeopathic products containing an active ingredient or ingredients officially included in the HPUS, packaged with statements of: (1) the specific diseases, ailments or their symptoms for which the product is to be used; (2) the concentration of active substance or substances contained therein; (3) dosage; and (4) mode of application in accordance with the requirements of the FFDCA?

**LAW AND ANALYSIS**

Merchandise is classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) in accordance with the General Rules of Interpretation (GRIs). The systematic detail of the HTSUS is such that virtually all goods are classified by application of GRI 1, that is, according to the terms of the headings of the tariff schedule and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied in order.

In understanding the language of the HTSUS, the Harmonized Commodity Description and Coding System Explanatory Notes may be utilized. The Explanatory Notes (ENs), although not dispositive or legally binding, provide a commentary on the scope of each heading of the HTSUS, and are the official interpretation of the Harmonized System at the international level. See T.D. 89-80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The HTSUS provisions under consideration are as follows:

<b>2106</b>	Food preparations not elsewhere specified or included:
2106.90	Other:
	Other:
2106.90.99	Other
* * *	* *
<b>3004</b>	Medicaments (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:
* * *	* *
3004.90	Other:
3004.90.91	Other:
3004.90.9190	Other

Both headings of the HTSUS under consideration are principal use provisions.

The principal use of the class or kind of goods to which an import belongs is controlling, not the principal use of the specific import. *Group Italglass U.S.A., Inc. v. United States*, 17 C.I.T. 1177, 1177, 839 F. Supp. 866, 867 (1993). "Principal use" is defined as the use "which exceeds any other single use." *Conversion of the Tariff Schedules of the United States Annotated Into the Nomenclature Structure of the Harmonized System*: Submitting Report at 34–35 (USITC Pub. No. 1400) (June 1983). As a result, "the fact that the merchandise may have numerous significant uses does not prevent the Court from classifying the merchandise according to the principal use of the class or kind to which the merchandise belongs." *Lenox Coll.*, 20 C.I.T., Slip Op. 96–30.

When applying a "principal use" provision, the Court must ascertain the class or kind of goods which are involved and decide whether the subject merchandise is a member of that class. See *supra* Additional US Rule of Interpretation 1 to the HTSUS. In determining the class or kind of goods, the Court examines factors which may include: (1) the general physical characteristics of the merchandise; (2) the expectation of the ultimate purchasers; (3) the channels of trade in which the merchandise moves; (4) the environment of the sale (e.g. the manner in which the merchandise is advertised and displayed); (5) the usage of the merchandise; (6) the economic practicality of so using the import; and (7) the recognition in the trade of this use. *United States v. Carborundum Co.*, 63 C.C.P.A. 98, 102, 536 F.2d 373, 377, cert. denied, 429 U.S. 979, 50 L. Ed. 2d 587, 97 S. Ct. 490 (1976); see also *Lenox Coll.*, 20 C.I.T., Slip Op. 96–30, at page 5.

*E. M. Chemicals v. United States*, 20 C.I.T. 382, 923 F. Supp. 202 (1996 Ct. Intl. Trade). Therefore, the determinative issue is whether these homeopathic products, which are regulated as drugs under the FDCA, belong to the class or kind of good that is principally prepared for therapeutic or prophylactic use or whether they belong to the class or kind of good that is principally used as a dietary supplement.

Medicaments principally prepared for therapeutic or prophylactic use in the U.S. are packaged for oral, parenteral (by injection), or dermatological administration. The ultimate purchaser expects that the substance will cure their condition or reduce its symptoms. The merchandise is regulated by the FDA as a drug and typically sold in pharmacies, over the counter or by prescription only or administered by health care personnel in hospitals or clinics. The merchandise is used according to a strict dosage schedule usually with a time limit on the recommended use.

By contrast, food supplements encompass a much more expansive group of items. They simply must be prepared for human consumption. As such, they are packaged for oral ingestion only as a capsule, tablet, powder or liquid. They are put up in packaging with indications that they maintain general health or well-being. The merchandise is often used daily without a strict dosage schedule or time limit recommended.

The internet web page of the HPUS, states, in pertinent part, the following:

Homeopathy is the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people. . . . Any substance may be considered a homeopathic medicine if it has known 'homeopathic prov-

ings' and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States.

One of the principal concepts of Homeopathy is the "Law of Infinitesimals." This principal holds that the smaller the dose of the substance, the more powerful will be its healing effects. For example, the starting substance is first mixed in alcohol to obtain a tincture. One drop of the tincture is mixed with 99 drops of alcohol (to achieve a ration of 1:100) and the mixture is strongly shaken. This shaking process is known as succussion. This bottle is labeled as "1C" or "2X." One drop of this 1C is then mixed with 100 drops of alcohol and the process is repeated to make 2C. By the time 3C (6X) is reached, the dilution is 1 part in 1 million.

In HQ 964882 we stated the following:

... [w]e are of the opinion that even though homeopathic products are marketed and labeled in a manner approved by the FDA indicating that they are intended to be used by purchasers for therapeutic purposes that unless such products contain a significantly detectable amount of that particular element or compound that is claimed to be an 'active ingredient,' such products are similar to placebos and should not be classified in chapter 30, HTSUS, as medicaments. We have determined that products which contain dilutions of active ingredients less than or equal to 16X or 8C may be classified in chapter 30, HTSUS, provided that Customs is able to detect significant levels of the 'active ingredient.' ... If the identifying component can be detected in quantities that can be considered effective, and that component is included in the HPUS, and the product is labeled in accordance with FDA guidelines, then Customs will concede classification in heading 3004, HTSUS.

However, upon further consideration, we no longer are of the view that the relevant standard in classifying homeopathic products is our ability to detect the presence of the active ingredient. Homeopathic products are considered to be drugs by the FDA. They all must comply with the standards listed in the HPUS. They all must be packaged with statements of the specific diseases, ailments or their symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the recommended dosage and the mode of application. They are all marketed and sold in relation to a disease, condition, or ailment which they purport to treat. If the condition is a very serious one, e.g. cancer, they are sold only by prescription. Hence, we find that in the context of homeopathic products, the outcome of the principal use test described above should not be based on the degree of dilution of the active ingredient in the homeopathic product. Therefore, we no longer believe that classifying homeopathic products according to the dilution of the active ingredient is correct.

**HOLDING:**

Accordingly, homeopathic products, which are considered by the FDA as drugs because they contain an active ingredient or ingredients officially included in the HPUS, and are packaged with statements of the specific diseases, ailments or their symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the recommended dosage and the mode of application, are classified in subheading 3004.90.9090, HTSUSA, the provision for "Medicaments (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: Other: Other: Other.”

Under *San Francisco Newspaper Printing Co. v. United States*, 9 CIT 517, 620 F. Supp. 738 (1985), the liquidation of the entries covering the merchandise which was the subject of Protest 2720-00-100769 was final on both the protestant and CBP. Therefore, this decision has no effect on those entries.

**EFFECT ON OTHER RULINGS:**

HQ 964882, dated September 26, 2002, is revoked.

MYLES B. HARMON,  
*Director,*  
*Commercial Rulings Division.*

[ATTACHMENT D]

DEPARTMENT OF HOMELAND SECURITY,  
BUREAU OF CUSTOMS AND BORDER PROTECTION,

HQ 967363  
CLA-2 RR:CR:GC 967363AM  
CATEGORY: Classification  
TARIFF NO.: 3004.90.9090

MS. HEATHER C. LITMAN  
STEIN, SHOSTAK, SHOSTAK & O'HARA  
515 South Figueroa St., Ste 1200  
Los Angeles, CA 90071-3329

RE: HQ 964188; Homeopathic Products

DEAR MS. LITMAN:

This is in reference to Headquarters Ruling Letters (HQ) 964188, dated April 3, 2002, regarding the classification of “Drink Ease” and “No Jet Lag,” pursuant to the Harmonized Tariff Schedule of the United States (HTSUS). In reviewing a similar matter, we have reviewed this ruling and find it to be incorrect. We propose to revoke it.

**FACTS:**

HQ 964188 ruled on Protest 2720-00-100187, filed by counsel on behalf of Global Source. “Drink Ease” and “No Jet Lag” are marketed as homeopathic drugs. Each of the products is packaged for retail sale with 30 tablets in a safety sealed blister strip. The outer package is labeled in accordance with regulations of the Food and Drug Administration (FDA) with active ingredient names and potencies, indications, warnings and dosage information. Both products are compressed tablets made of sorbitol (a non-nutritive sweetening agent commonly used to make tablets), sterilized talc and magnesium stearate (both are inactive ingredients used as lubricants/separators in tablet compression). Equal amounts of five homeopathic active ingredients which have been processed by the manufacturer according to rules established by the Homeopathic Pharmacopoeia of the United States (HPUS) are sprayed onto the tablets. The active ingredients have homeopathic potencies of “30C.” “Drink Ease” is marketed for the relief of alcoholic hang-

overs and contains *Avena Sativa* (oats), *Capsicum Annuum* (pepper), *Nux Vomica* (identified as nutmeg, actually strychnine), *Veratrum Album* (white hellebore) and *Zinc Metallicum* (zinc metal). "No Jet Lag" is marketed for relief of tiredness associated with air travel and contains *Arnica Montana* (leopard's bane), *Bellis Perennis* (daisy), *Chamomilla* (wild chamomile), *Ipecacuanha* (ipecac) and *Lycopodium* (clubmoss).

The Federal Food Drug and Cosmetic Act ("FFDCA") (21 U.S.C. §§ 301 *et seq.*), states, in pertinent part, that "the term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C) (21 U.S.C. § 321(g)(1)).

In 1988, FDA issued a compliance policy guide ("CPG"), entitled "Conditions under Which Homeopathic Drugs May be Marketed" (Sec. 400.400 CPG 7132.25), describing FDA's regulatory approach toward homeopathic medicines. The CPG explains that Homeopathic products must meet the standards for strength, quality, and purity set forth in the Homeopathic Pharmacopoeia (21 U.S.C. 351). Additionally, product labeling must comply with the labeling provisions of Sections 502 and 503 of the FFDCA and Part 201 (21 CFR 201). Each product must bear the name and place of business of the manufacturer, adequate directions for use, a statement of the quantity and amount of ingredients in the product expressed in homeopathic terms, indications for use, and warnings as described in 21 CFR 201 *et seq.* The CPG explains that homeopathic products are subject to FDA enforcement if they are misbranded, or violate any FDA adulteration or promotional restrictions. Furthermore, Section 503(b) of the FFDCA mandates that homeopathic products offered for conditions not amenable to over-the-counter use must be marketed as prescription products. Lastly, the FDA does not regulate these products under the Dietary Supplement Health and Education Act of 1994, (21 U.S.C. 301 *et seq.*), which amended the FFDCA by adding provisions to regulate dietary supplements as it does food.

#### **ISSUE:**

What is the classification of homeopathic products containing an active ingredient or ingredients officially included in the HPUS, packaged with statements of: (1) the specific diseases, ailments or their symptoms for which the product is to be used; (2) the concentration of active substance or substances contained therein; (3) dosage; and (4) mode of application in accordance with the requirements of the FFDCA?

#### **LAW AND ANALYSIS**

Merchandise is classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) in accordance with the General Rules of Interpretation (GRIs). The systematic detail of the HTSUS is such that virtually all goods are classified by application of GRI 1, that is, according to the terms of the headings of the tariff schedule and any relative Section or Chapter Notes. In the event that the goods cannot be classified solely on the basis of GRI 1, and if the headings and legal notes do not otherwise require, the remaining GRIs may then be applied in order.

In understanding the language of the HTSUS, the Harmonized Commodity Description and Coding System Explanatory Notes may be utilized. The Explanatory Notes (ENs), although not dispositive or legally binding, provide a commentary on the scope of each heading of the HTSUS, and are the official interpretation of the Harmonized System at the international level. See T.D. 89-80, 54 Fed. Reg. 35127, 35128 (August 23, 1989).

The HTSUS provisions under consideration are as follows:

**2106** Food preparations not elsewhere specified or included

2106.90 Other:

Other

Other

Other

Other

2106.90.99 Other

**3004** Medicaments (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:

\* \* \*

3004.90 Other:

3004.90.90 Other

3004.90.9090 Other

Both headings of the HTSUS under consideration are principal use provisions.

The principal use of the class or kind of goods to which an import belongs is controlling, not the principal use of the specific import. *Group Italglass U.S.A., Inc. v. United States*, 17 C.I.T. 1177, 1177, 839 F. Supp. 866, 867 (1993). "Principal use" is defined as the use "which exceeds any other single use." *Conversion of the Tariff Schedules of the United States Annotated Into the Nomenclature Structure of the Harmonized System*: Submitting Report at 34-35 (USITC Pub. No. 1400) (June 1983). As a result, "the fact that the merchandise may have numerous significant uses does not prevent the Court from classifying the merchandise according to the principal use of the class or kind to which the merchandise belongs." *Lenox Coll.*, 20 C.I.T., Slip Op. 96-30.

When applying a "principal use" provision, the Court must ascertain the class or kind of goods which are involved and decide whether the subject merchandise is a member of that class. See *supra* Additional US Rule of Interpretation 1 to the HTSUS. In determining the class or kind of goods, the Court examines factors which may include: (1) the general physical characteristics of the merchandise; (2) the expectation of the ultimate purchasers; (3) the channels of trade in which the merchandise moves; (4) the environment of the sale (e.g. the manner in which the merchandise is advertised and displayed); (5) the usage of the merchan-

dise; (6) the economic practicality of so using the import; and (7) the recognition in the trade of this use. *United States v. Carborundum Co.*, 63 C.C.P.A. 98, 102, 536 F.2d 373, 377, cert. denied, 429 U.S. 979, 50 L. Ed. 2d 587, 97 S. Ct. 490 (1976); see also *Lenox Coll.*, 20 C.I.T., Slip Op. 96-30, at page 5.

*E. M. Chemicals v. United States*, 20 C.I.T. 382, 923 F. Supp. 202 (1996 Ct. Intl. Trade). Therefore, the determinative issue is whether these homeopathic products, which are regulated as drugs under the FFDCA, belong to the class or kind of good that is principally prepared for therapeutic or prophylactic use or whether they belong to the class or kind of good that is principally used as a dietary supplement.

Medicaments principally prepared for therapeutic or prophylactic use in the U.S. are packaged for oral, parenteral (by injection), or dermatological administration. The ultimate purchaser expects that the substance will cure their condition or reduce its symptoms. The merchandise is regulated by the FDA as a drug and typically sold in pharmacies, over the counter or by prescription only or administered by health care personnel in hospitals or clinics. The merchandise is used according to a strict dosage schedule usually with a time limit on the recommended use.

By contrast, food supplements encompass a much more expansive group of items. They simply must be prepared for human consumption. As such, they are packaged for oral ingestion only as a capsule, tablet, powder or liquid. They are put up in packaging with indications that they maintain general health or well-being. The merchandise is often used daily without a strict dosage schedule or time limit recommended.

The internet web page of the HPUS, states, in pertinent part, the following:

Homeopathy is the art and science of healing the sick by using substances capable of causing the same symptoms, syndromes and conditions when administered to healthy people. . . . Any substance may be considered a homeopathic medicine if it has known 'homeopathic provings' and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States.

One of the principal concepts of Homeopathy is the "Law of Infinitesimals." This principal holds that the smaller the dose of the substance, the more powerful will be its healing effects. For example, the starting substance is first mixed in alcohol to obtain a tincture. One drop of the tincture is mixed with 99 drops of alcohol (to achieve a ration of 1:100) and the mixture is strongly shaken. This shaking process is known as succussion. This bottle is labeled as "1C" or "2X." One drop of this 1C is then mixed with 100 drops of alcohol and the process is repeated to make 2C. By the time 3C (6X) is reached, the dilution is 1 part in 1 million.

In HQ 964882 we stated the following:

. . . [w]e are of the opinion that even though homeopathic products are marketed and labeled in a manner approved by the FDA indicating that they are intended to be used by purchasers for therapeutic purposes that unless such products contain a significantly detectable amount of that particular element or compound that is claimed to be an 'active ingredient,' such products are similar to placeboes and should not be clas-

sified in chapter 30, HTSUS, as medicaments. We have determined that products which contain dilutions of active ingredients less than or equal to 16X or 8C may be classified in chapter 30, HTSUS, provided that Customs is able to detect significant levels of the 'active ingredient.' . . . If the identifying component can be detected in quantities that can be considered effective, and that component is included in the HPUS, and the product is labeled in accordance with FDA guidelines, then Customs will concede classification in heading 3004, HTSUS.

However, upon further consideration, we no longer are of the view that the relevant standard in classifying homeopathic products is our ability to detect the presence of the active ingredient. Homeopathic products are considered to be drugs by the FDA. They all must comply with the standards listed in the HPUS. They all must be packaged with statements of the specific diseases, ailments or their symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the recommended dosage and the mode of application. They are all marketed and sold in relation to a disease, condition, or ailment which they purport to treat. If the condition is a very serious one, e.g. cancer, they are sold only by prescription. Hence, we find that in the context of homeopathic products, the outcome of the principal use test described above should not be based on the degree of dilution of the active ingredient in the homeopathic product. Therefore, we no longer believe that classifying homeopathic products according to the dilution of the active ingredient is correct.

**HOLDING:**

Accordingly, homeopathic products, which are considered by the FDA as drugs because they contain an active ingredient or ingredients officially included in the HPUS, and are packaged with statements of the specific diseases, ailments or their symptoms for which the product is to be used, the concentration of active substance or substances contained therein, the recommended dosage and the mode of application, are classified in subheading 3004.90.9090, HTSUSA, the provision for "Medicaments (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: Other: Other: Other."

Under *San Francisco Newspaper Printing Co. v. United States*, 9 CIT 517, 620 F. Supp. 738 (1985), the liquidation of the entries covering the merchandise which was the subject of Protest 2720-00-100187 were final on both the protestant and U.S. Customs and Border Protection. Therefore, this decision has no effect on those entries.

**EFFECT ON OTHER RULINGS:**

HQ 964188, dated April 3, 2002 is revoked.

MYLES B. HARMON,  
*Director,*  
*Commercial Rulings Division.*

