

Bureau of Customs and Border Protection

General Notices

AGENCY INFORMATION COLLECTION ACTIVITIES: CANADIAN BOAT LANDING PERMIT (I-68)

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

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Canadian Boat Landing Permit. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (69 FR 59605–59606) on October 5, 2004, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Homeland Security Desk Officer, Washington, D.C. 20503. Additionally comments may be submitted to OMB via facsimile to (202) 395–6974.

SUPPLEMENTARY INFORMATION:

The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing informa-

tion collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Your comments should address one of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Canadian Border Boat Landing Permit

OMB Number: 1651-0108

Form Number: Form I-68

Abstract: This collection involves information from individuals who desire to enter the United States from Canada in a small pleasure craft.

Current Actions: This is an extension of a currently approved information collection.

Affected Public: Individuals or Households

Estimated Number of Respondents: 68,000

Estimated Time Per Respondent: 10 minutes

Estimated Total Annual Burden Hours: 11,288

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.2.C, Washington, D.C. 20229, at 202-344-1429.

Dated: November 30, 2004

TRACEY DENNING,
*Agency Clearance Officer,
Information Services Branch.*

**AGENCY INFORMATION COLLECTION ACTIVITIES:
CBP REGULATIONS FOR CUSTOMSHOUSE BROKERS**

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

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: CBP Regulations for Customshouse Brokers. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (69 FR 56449) on September 21, 2004, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Treasury Desk Officer, Washington, D.C. 20503. Additionally comments may be submitted to OMB via facsimile to (202) 395-6974.

SUPPLEMENTARY INFORMATION:

The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L.104-13). Your comments should address one of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;

- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: CBP Regulations for Customhouse Brokers

OMB Number: 1651-0034

Form Number: N/A

Abstract: This information is collected to ensure regulatory compliance for Customhouse brokers.

Current Actions: This submission is being submitted to extend the expiration date with a change in the burden hours.

Type of Review: Extension (with change)

Affected Public: Businesses, Individuals, Institutions

Estimated Number of Respondents: 3800

Estimated Time Per Respondent: 1.4 hours

Estimated Total Annual Burden Hours: 5450

Estimated Total Annualized Cost on the Public: \$545,000

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.2.C, Washington, D.C. 20229, at 202-344-1429.

Dated: November 30, 2004

TRACEY DENNING,
*Agency Clearance Officer,
Information Services Branch.*

[Published in the Federal Register, December 7, 2004 (69 70698)]

**AGENCY INFORMATION COLLECTION ACTIVITIES:
COMMERCIAL INVOICE**

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

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Commercial Invoice. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be

extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (69 FR 56447) on September 21, 2004, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Homeland Security Desk Officer, Washington, D.C. 20503. Additionally comments may be submitted to OMB via facsimile to (202) 395-6974.

SUPPLEMENTARY INFORMATION:

The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L.104-13). Your comments should address one of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Commercial Invoice
OMB Number: 1651-0090
Form Number: N/A

Abstract: The collection of the Commercial Invoice is necessary for the proper assessment of duties. The invoice(s) is attached to the

CBP Form 7501. The information, which is supplied by the foreign shipper, is used to ensure compliance with statutes and regulations.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change)

Affected Public: Businesses, Institutions

Estimated Number of Respondents: 46,500,000

Estimated Time Per Respondent: 10 seconds

Estimated Total Annual Burden Hours: 130,200

Estimated Total Annualized Cost on the Public:
\$2,050,650.00

Estimated Number of Respondents: 34,500

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.2.C, Washington, D.C. 20229, at 202-344-1429.

Dated: November 30, 2004

TRACEY DENNING,
Agency Clearance Officer;
Information Services Branch.

[Published in the Federal Register, December 7, 2004 (69 70700)]

**AGENCY INFORMATION COLLECTION ACTIVITIES:
COST SUBMISSION**

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

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Cost Submission. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (69 FR 56449) on September 21, 2004, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Homeland Security Desk Officer, Washington, D.C. 20503. Additionally comments may be submitted to OMB via facsimile to (202) 395-6974.

SUPPLEMENTARY INFORMATION:

The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L.104-13). Your comments should address one of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Cost Submission

OMB Number: 1651-0028

Form Number: Form CBP-247

Abstract: These Cost Submissions, Form CBP-247, are used by importers to furnish cost information to CBP which serves as the basis to establish the appraised value of imported merchandise.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change)

Affected Public: Businesses, Individuals, Institutions

Estimated Number of Respondents: 1,000
Estimated Time Per Respondent: 50 hours
Estimated Total Annual Burden Hours: 50,000
Estimated Total Annualized Cost on the Public: \$1,089,000

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.2.C, Washington, D.C. 20229, at 202-344-1429.

Dated: November 30, 2004

TRACEY DENNING,
*Agency Clearance Officer,
Information Services Branch.*

[Published in the Federal Register, December 7, 2004 (69 70698)]

**AGENCY INFORMATION COLLECTION ACTIVITIES:
Declaration of Ultimate Consignee That Articles Were
Exported for Temporary Scientific or Educational Purposes**

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

ACTION: Proposed collection; comments requested.

SUMMARY: The Bureau of Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: U.S./Israel Free Trade Agreement. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (69 FR 56448) on September 21, 2004, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before January 6, 2005.

ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Af-

fairs, Attention: Department of Homeland Security Desk Officer, Washington, D.C. 20503. Additionally comments may be submitted to OMB via facsimile to (202) 395-6974.

SUPPLEMENTARY INFORMATION:

The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L.104-13). Your comments should address one of the following four points:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agencies/components estimate of the burden of The proposed collection of information, including the validity of the methodology and assumptions used;
- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Declaration of Ultimate Consignee That Articles Were Exported for Temporary Scientific or Educational Purposes

OMB Number: 1651-0036

Form Number: N/A

Abstract: The "Declaration of Ultimate Consignee that Articles were Exported for Temporary Scientific or Educational Purposes" is used to provide duty free entry under conditions when articles are temporarily exported solely for scientific or educational purposes.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change)

Affected Public: Businesses, Individuals, Institutions

Estimated Number of Respondents: 55

Estimated Time Per Respondent: 30 minutes

Estimated Total Annual Burden Hours: 27

Estimated Total Annualized Cost on the Public: \$754.65

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.2.C, Washington, D.C. 20229, at 202-344-1429.

Dated: November 30, 2004

TRACEY DENNING,
*Agency Clearance Officer,
Information Services Branch.*

[Published in the Federal Register, December 7, 2004 (69 70699)]

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

Washington, DC, December 8, 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 LETTERS AND TREATMENT RELATING TO THE TARIFF CLASSIFICATION OF HOMEOPATHIC PRODUCTS

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

ACTION: Notice of revocation of tariff classification ruling letters 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 the Bureau of Customs and Border Protection (CBP) is revoking two rulings concerning the tariff classification of homeopathic products, under the Harmonized Tariff Schedule of the United States (HTSUS). Similarly, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. Notice of the proposed revocation of the rulings was published on October 27, 2004, in Volume 38, Number 44, of the *Customs Bulletin*. Twenty-two comments were received in support of this notice.

EFFECTIVE DATE: This notice is generally effective for merchandise entered or withdrawn from warehouse for consumption on or after February 20, 2005.

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 CBP 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 CBP 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 CBP 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, CBP published a notice in the October 27, 2004, *Customs Bulletin*, Volume 38, Number 44, proposing to revoke Headquarters Ruling Letters (HQ) 964882, dated September 26, 2002, and 964188, dated April 3, 2002, and to revoke any treatment accorded to substantially identical merchandise. Twenty-two comments were received in support of this notice.

In HQ 964882 and HQ 964188, 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 Homeopathic Pharmacopoeia of the United States (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.

As stated in the proposed notice, this revocation will cover any rulings on this issue which 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 issue 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 Title VI, CBP is revoking any treatment previously accorded by CBP to substantially identical transactions. This treatment may, among other reasons, have been 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 involving the same or similar merchandise, or the importer's or CBP previous interpretation of the Harmonized Tariff Schedule of the United States. Any person involved in substantially identical transactions should have advised CBP during the notice period. An importer's reliance on a treatment of substantially identical transactions or on a specific ruling concerning the merchandise covered by this notice which was not identified in this notice may raise issues of reasonable care on the part of the importer or its agents for importations subsequent to the effective date of this final decision.

CBP, pursuant to section 625(c)(1), is revoking HQ 964882 and HQ 964188, and any other ruling not specifically identified, to reflect the proper classification of the merchandise pursuant to the analysis set forth in Headquarters Ruling Letters (HQ) 967075 and HQ 967363, set forth as attachments "A" and "B" to this notice. Additionally, pursuant to section 625(c)(2), CBP is revoking any treatment previously accorded by CBP to substantially identical transactions.

In accordance with 19 U.S.C. 1625(c), these rulings will generally become effective 60 days after publication in the *Customs Bulletin*.

Dated: December 6, 2004

MYLES B. HARMON,
Director,
Commercial Rulings Division.

Attachments

[ATTACHMENT A]

DEPARTMENT OF HOMELAND SECURITY,
BUREAU OF CUSTOMS AND BORDER PROTECTION,
HQ 967075
December 6, 2004
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 are revoking it.

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 published a notice in the October 27, 2004, *Customs Bulletin*, Volume 38, Number 44, proposing to revoke Headquarters Ruling Letters (HQ) 964882, dated September 26, 2002, and 964188, dated April 3, 2002, and to revoke any treatment accorded to substantially identical merchandise. Twenty-two comments were received in support of this notice.

FACTS:

HQ 964882 ruled on Protest 2720-00-100769, filed by counsel on behalf of Boiron USA. The 45 entries covering merchandise that were the subject of that 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 the 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:

2106 Food preparations not elsewhere specified or included:
 2106.90 Other:
 Other:
 Other:
 Other:
 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:
 3004.90.91 Other:
 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 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 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 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 ratio 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 3004.90.9190, 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.

However, in a comment, dated November 23, 2004, you requested, on behalf of Boiron, USA, that the decision be made effective immediately upon publication of the final decision. Pursuant to 19 CFR § 177.12(e)(2)(ii), this ruling is effective upon the date of its publication in the *Customs Bulletin*.

EFFECT ON OTHER RULINGS:

HQ 964882, dated September 26, 2002, is revoked. Furthermore, to the extent that HQ 964494, dated August 28, 2002, issued to Bioforce AG, or any other ruling, contradicts in *dicta*, or otherwise, the analysis set forth above

with regard to the classification of homeopathic products, that analysis no longer represents the position of CBP.

MYLES B. HARMON,
Director,
Commercial Rulings Division.

[ATTACHMENT B]

DEPARTMENT OF HOMELAND SECURITY,
BUREAU OF CUSTOMS AND BORDER PROTECTION,
HQ 967363
December 6, 2004
CLA-2 RR:CR:GC 967363AM
CATEGORY: Classification
TARIFF NO.: 3004.90.9190

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 are revoking it.

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 published a notice in the October 27, 2004, *Customs Bulletin*, Volume 38, Number 44, proposing to revoke Headquarters Ruling Letters (HQ) 964882, dated September 26, 2002, and 964188, dated April 3, 2002, and to revoke any treatment accorded to substantially identical merchandise. Twenty-two comments were received in support of this notice.

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 (ippecac) 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:

3004.90.91 Other:

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 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.

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HOLDING:

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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 was final on both the protestant and CBP. Therefore, this decision has no effect on those entries.

EFFECT ON OTHER RULINGS:

HQ 964188, dated April 3, 2002 is revoked. Furthermore, to the extent that HQ 964494, dated August 28, 2002, issued to Bioforce AG, or any other ruling, contradicts in *dicta*, or otherwise, the analysis set forth above with regard to the classification of homeopathic products, that analysis no longer represents the position of CBP.

MYLES B. HARMON,
Director,
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