



Ottawa, October 13, 2006

MEMORANDUM D10-14-30

In Brief

TARIFF CLASSIFICATION OF MEDICAMENTS INCLUDING NATURAL HEALTH PRODUCTS

1. This Departmental Memorandum updates D10-14-30, dated August 20, 2004. The memorandum explains the Canada Border Services Agency's policy for the tariff classification of medicaments, including natural health products, based on jurisprudence of the Canadian International Trade Tribunal and the Federal Court of Appeal.
2. Paragraph 15 has been added in order to specify the World Customs Organization Explanatory Notes and Compendium of Classification Opinions that Canada is not able to apply as a result of this policy.
3. Paragraph 16 contains information about whom to contact for further information



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MEMORANDUM D10-14-30

TARIFF CLASSIFICATION OF MEDICAMENTS INCLUDING NATURAL HEALTH PRODUCTS

This Memorandum explains the Canada Border Services Agency's (CBSA) policy for the tariff classification of medicaments, including natural health products, under headings 30.03 and 30.04 of the *Customs Tariff*. The policy is based on jurisprudence for classifying medicaments resulting from decisions of the Canadian International Trade Tribunal and the Federal Court of Appeal.

Legislation

Customs Tariff

Legal Notes

Section VI

Note 1.

(a) Goods (other than radioactive ores) answering to a description in heading 28.44 or 28.45 are to be classified in those headings and in no other heading of the Nomenclature.

(b) Subject to paragraph (a) above, goods answering to a description in heading 28.43 or 28.46 are to be classified in those headings and in no other heading of this Section.

Note 2.

Subject to Note 1 above, goods classifiable in heading 30.04, 30.05, 30.06, 32.12, 33.03, 33.04, 33.05, 33.06, 33.07, 35.06, 37.07 or 38.08 by reason of being put up in measured doses or for retail sale are to be classified in those headings and in no other heading of the Nomenclature.

Chapter 30

Note 1.

1. This Chapter does not cover:

(a) Foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (Section IV);

(b) Plasters specially calcined or finely ground for use in dentistry (heading 25.20);

(c) Aqueous distillates or aqueous solutions of essential oils, suitable for medicinal uses (heading 33.01);

(d) Preparations of headings 33.03 to 33.07, even if they have therapeutic or prophylactic properties;

(e) Soap or other products of heading 34.01 containing added medicaments;

(f) Preparations with a basis of plaster for use in dentistry (heading 34.07); or

(g) Blood albumin not prepared for therapeutic or prophylactic uses (heading 35.02).

HEADINGS

30.03 Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.

30.04 Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

GUIDELINES AND GENERAL INFORMATION

Administrative Policy

1. A product can be classified as a medicament under heading 30.03 or 30.04 if it satisfies the following:

(a) meets the terms of the heading and any relative legal note; and

(b) evidence attests to the product's therapeutic or prophylactic use; and

(c) the goods are presented as a therapeutic or prophylactic product.

Guidelines

2. The following information will help in determining the tariff classification of medicaments consistent with decisions of the Canadian International Trade Tribunal (CITT) and the Federal Court of Appeal. In this Memorandum the word "medicament" includes natural health products.

3. Definitions:

- (a) ailment: “an illness of a trivial nature”^{1*}
- (b) curative: “having remedial properties, helping to cure”^{2*}
- (c) disease: “an unhealthy condition; a particular malady”^{3*}
- (d) food: “substance(s) taken into the body to maintain life and growth”⁴
- (e) medicament: “[a] substance used in curative treatment”⁵
- (f) prophylactic: “tending to prevent disease or other misfortune”⁶
- (g) therapeutic: “curative; of the healing art”⁷

* Definitions cited by the CITT

4. In their decisions, the CITT and the Federal Court of Appeal made a number of observations and drew certain conclusions in order to classify medicaments in the Harmonized System (HS) as follows:

(a) There is no requirement in the Harmonized System’s legal notes, in the provisions of headings 30.03 and 30.04, or in the supporting *Explanatory Notes*, that a certain level of medicinal ingredients must be in a product in order for it to be classified as a medicament. Furthermore, there is no burden to scientifically prove that the product actually cures a disease, illness, or ailment. The terms of the heading do not require scientific proof of medical efficacy.

However, the intent of headings 30.03 and 30.04 is to provide for goods that are in the nature of medicaments. In accordance with the terms of the headings, there must be some therapeutic or prophylactic (medicinal) use for the product. Simply declaring that a product is a medicament does not qualify it for classification under heading 30.03 or 30.04.

(b) Marketing, packaging, use, and other evidence (e.g. from a professional medical practitioner or a recognized text) that can attest to a product’s medicinal purpose (therapeutic or prophylactic) are important determining factors in classifying the product under

heading 30.03 or 30.04. There must be some indication as to the use of the product in the preventing or treating of a disease, illness, or ailment.

Examples

- St. John’s wort oil extract, mixed with olive oil, is used to treat such things as mild to moderate depression, tension headaches and insomnia. When imported in bulk it is classified under heading 30.03, or under heading 30.04 when put up in measured doses or in forms or packings for retail sale.
- Re-distilled water is classified under heading 28.51. However, when put up as a medicament in measured doses or in forms or packings for retail sale, for use in the treatment of a disease, it is classified in heading 30.04.⁸
- Sulphur put up for retail sale for a therapeutic purpose (e.g. as a scabicide) is classified as a medicament under heading 30.04 and not under heading 25.03 or 28.02.⁹

(c) Medicaments are generally not included in the common understanding of the term food. However, certain nutritional dietary supplements, sometimes considered food preparations, can be classified in heading 30.04 as a medicament. This is the case when the supplement is expressly for use in the prevention or treatment of a disease, illness or ailment and put up in a form specified in that heading.

For example, garlic powder packaged for use in preparing food (i.e. for flavouring) is classified in heading 07.12. However, when garlic powder is prepared as tablets (measured doses), or in another form or packing for retail sale, and sold for its curative properties (e.g. in the treatment of cardiovascular disease), the garlic is classified as a medicament under heading 30.04.

5. Throat pastilles or cough drops can be classified under heading 30.04 when put up in measured doses or in forms or packings for retail sale provided they contain a medicinal ingredient(s) such that each pastille or cough drop has a therapeutic or prophylactic use.

1 The New Lexicon Webster’s Dictionary of the English language, (New York: Lexicon Publications, 1987).

2 Ibid.

3 Ibid.

4 The Concise Oxford Dictionary, 7th edition

5 Ibid.

6 Ibid.

7 Ibid.

8 HS Explanatory Note (a) to heading 30.04, page 571.

9 HS Explanatory Note to legal note 2 to Section VI, page 258.

6. While national health authorities may define medicaments differently, it is uncontested that vitamins, and vitamin preparations, have therapeutic and prophylactic uses. Vitamins have been proven effective in the treatment and prevention of certain diseases (e.g. vitamin C for scurvy and vitamin B12 for pernicious anaemia) and can thus be classified as a medicament. However, the vitamins considered as medicaments in this memorandum do not include the goods provided for in heading 29.36. However, vitamin C of heading 29.36 for example, can be classified in heading 30.04 by reason of it being put up in measured doses or in forms or packings for retail sale for a therapeutic or prophylactic purpose.¹⁰

7. If a vitamin, or vitamin preparation, is ingested to reverse or prevent (therapeutic or prophylactic) a deficiency that may lead to a disease, illness, or ailment, it follows that the purpose of ingesting the product is to reverse or prevent that malady. It is suggestive though not conclusive in all cases that such vitamin products, intended for human or animal use, are medicaments.

8. Declaring that a product is a medicament does not make it so. There must be some evidence to support such a claim. Trade or technical publications issued by the manufacturer or producer can help in making a determination. Similarly, technical papers published in professional journals and authored by health practitioners may also provide information about a product's therapeutic or prophylactic uses. This includes an opinion of an expert or specialist in the particular disease, illness or ailment.

9. Goods considered by some to be medicaments, such as certain traditional natural health products, are excluded from headings 30.03 and 30.04. For example, diabetic or fortified foods, food supplements for general health and well-being and tonic beverages (tonic wine with herbs) etc., are specifically excluded (see legal Note 1 to Chapter 30) even though they may be considered a medicament by their use and reputation in traditional herbal medicine.

General Information

10. The simplest way to determine if a product is for therapeutic or prophylactic use is to read the label. If the label does not provide the necessary information, or if the product's therapeutic or prophylactic benefits are not clear, consulting with the importer or manufacturer is recommended.

11. Useful information on the therapeutic or prophylactic purpose of a medicament might be found in a recognized text. A recognized text is, for example, a publication mentioned in Schedule B of the *Food and Drugs Act*, the Compendium of Pharmaceuticals and Specialties (CPS), the

Merck Index, or a recognized refereed medical paper, etc. Recognized refereed papers are articles in recognized journals of medicine, such as the *International Journal of Medicine*, which have been reviewed by a qualified individual. Not all technical papers published in recognized journals are refereed. Papers that are not refereed may need verification.

12. For this policy, the meaning of the term "professional medical practitioner" is broadly defined. The term refers not only to physicians, but also to chiropractors, dentists, naturopaths, nurses, pharmacists, and physical therapists etc.

13. While conditions such as tension headaches, insomnia, gastrointestinal disorder, external wounds and other maladies may not be considered true diseases or illnesses, they clearly constitute various forms of disorders or ailments.

14. Additional information, such as drug product monographs, can be found on Health Canada's Web site. Drug product monographs identify the recommended use or purpose for ingredients based on the Natural Health Product Directorate's evaluation of the safety and efficacy data.

15. In view of this policy, Canada is not able to apply the HS Explanatory Notes, relating to throat pastilles, and three Compendium Opinions, as follows:

HS Explanatory Notes:

heading 17.04 (v), page 150; heading 30.04, page 572

Compendium Opinions:

1704.90 (3) Throat pastilles or cough drops consisting essentially of sugars and flavouring agents, e.g., menthol, eucalyptol or peppermint oil, (without other active ingredients).

2106.90 (22) Vitamin C preparation (500 mg per tablet) put up for retail sale in a container holding 130 tablets, containing ascorbic acid, corn starch, cross-linked carboxymethyl cellulose sodium, cellulose, rose hips, stearic acid, lemon bioflavonoid complex, magnesium stearate and acerola. According to the label, the product is not intended to diagnose, treat, cure or prevent any disease.

2106.90 (24) Cough syrup in the form of an aqueous solution of an alcoholic strength by volume of 1.8 % vol, put up in a container of 100 ml (130 g). The product consists of honey, plant tinctures, glucose syrup, invert sugar syrup, cherry aroma, rose oil, sodium benzoate and purified water. According to the label, the product is recommended to be used against

¹⁰ Ibid.

respiratory catarrhal diseases and difficulty of bronchial mucus secretion. The content of active medicinal ingredients is, however, not sufficient to provide a recognisable and clinically proven therapeutic or prophylactic effect.

16. For additional information on this policy you may contact the senior program advisor in the Tariff Policy Division at 613-954-7019.

REFERENCES

<p>ISSUING OFFICE –</p> <p>Tariff Policy Division Trade Programs Directorate Canada Border Services Agency</p>	<p>HEADQUARTERS FILE –</p> <p>F258860/HS 3004.90</p>
<p>LEGISLATIVE REFERENCES –</p> <p><i>Customs Tariff</i></p>	<p>OTHER REFERENCES –</p> <p>CITT AP-94-199 Flora Distributors Ltd. and the DMNR AP-96-044 Hung Gay Enterprises Ltd. and the DMNR AP-96-117 Yves Ponroy Canada and the DMNR AP-97-002 Flora Manufacturing & Distributing Ltd. and the DMNR AP-97-010 Hilary's Distributing Ltd. and the DMNR AP-97-052 Flora Manufacturing & Distributing Ltd. and the DMNR AP-97-058 Flora Manufacturing & Distributing Ltd. and the DMNR AP-2002-038 to AP-2002-090 Pfizer Canada Inc. and the Commissioner of the CCRA</p> <p>FEDERAL COURT OF APPEAL Docket: A-97-98, A-671-98, A-632-98, A-633-98 DMNR and Yves Ponroy et. al. Docket: A-720-98 Flora Manufacturing & Distributing Ltd. and the DMNR</p> <p>WORLD CUSTOMS ORGANIZATION (est. 1952 as the Customs Co-operation Council) Harmonized Commodity Description and Coding System (HS) Third edition (2002) Compendium of Classification Opinions</p>
<p>SUPERSEDED MEMORANDA "D" –</p> <p>D10-14-30, August 20, 2004</p>	

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