



Ottawa, September 18, 2003

# CUSTOMS NOTICE N-536

## Tariff Classification of Vitamin Preparations as Medicaments

1. This Customs Notice explains the Canada Customs and Revenue Agency (CCRA) administrative policy regarding the tariff classification of vitamin preparations as medicaments under heading 30.04 of the *Customs Tariff*.
2. The policy is based on decisions of the Canadian International Trade Tribunal (CITT) and Federal Court of Appeal.
3. As a result of a decision of the Federal Court of Appeal, the CCRA has informed the World Customs Organization that it cannot comply with its classification opinion of a certain vitamin C preparation under heading 21.06.

### Legislation – Heading

**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.**

### Administrative Guidelines

4. This Notice provides guidance in determining when a vitamin preparation is classified as a medicament of heading 30.04 and to advise you that the World Customs Organization (WCO) Compendium Opinion **2106.90 (22)** is rendered null and void by a Federal Court decision and therefore not applicable.
5. The vitamin preparations contemplated in this Notice do not include the single vitamin compounds provided for in Chapter 29. Single vitamin compounds that are unmixed (with the exception of allowable additions specified in Note 1 to Chapter 29, such as stabilizers for transport or preservation) and not “...*put up in measured doses or in forms or packings for retail sale*”, are classified in Chapter 29 (heading 29.36).

6. The CCRA is of the view that, while there may be differing definitions of medicaments by different national health authorities, it is uncontested that vitamins have therapeutic and prophylactic value. Vitamins have been proven effective in the treatment and prevention of certain diseases (e.g. vitamin C for scurvy and vitamin B12 for pernicious anemia).

7. In order to simplify the classification of vitamin preparations in the *Customs Tariff*, those preparations which have been issued Drug Identification Numbers (DIN) from Health Canada can be considered as a medicament for the purposes of heading 30.04. The criteria to be met for issuing a DIN number for a vitamin is set out in Health Canada’s *Labelling Standard – Vitamin Supplements*. Guidelines for the preparation of a DIN submission can be found on the Health Canada website<sup>1</sup>.

8. This policy takes into consideration the vitamin content of the goods, the form in which the goods are presented, as well as contemplating any additional ingredients.

9. Health Canada’s *Labelling Standard* (ref.: II (a) **Pharmaceutical Quality**) requires the “medicinal” (vitamins) and “non-medicinal” ingredients meet, as a minimum, the standards described in the pharmaceutical reference publications referred to in Schedule B to the Food and Drugs Act. In addition the “non-medicinal” ingredients (ref.: III (d)(i) – **Nonmedical Ingredients**) must be restricted to those substances necessary for the formulation of the dosage form. The restriction on allowable nonmedical ingredients assures the goods retain the character of vitamin preparations.

10. With regards to the WCO Compendium Opinion **2106.90 (22)** concerning a vitamin C preparation put up for retail sale, the Federal Court reasoned that if the ingestion of vitamins prevents or reverses a deficiency that may lead to a disease or an ailment, the vitamin preparation is considered a medicament. In order to be consistent with the reasoning of the Court we classify the vitamin C preparation, enumerated in Compendium Opinion **2106.90 (22)**, in heading 30.04 and not in heading 21.06 as ruled by the WCO.

<sup>1</sup> <http://www.hc.gc.ca>

11. Further information may be obtained by contacting:

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