

Formalities required to market dietary supplements in the United States

With the assistance of the US Department of Commerce, we have recently been in correspondence with the U.S. Food and Drug Administration (FDA) concerning the formalities required by those proposing to market dietary supplements in the United States. FDA has confirmed the following:

- Dietary supplements do not require the FDA’s approval before marketing.
- The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(b)) requires that manufacturers and distributors who wish to market dietary supplements that contain “new dietary ingredients” (except for certain substances with a history of food use) notify the FDA about these ingredients.
- According to 21 U.S.C. 350b(c) the term “new dietary ingredient” refers to a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. It may be subject to the notification requirement in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.
- There is no authoritative list of dietary ingredients that were marketed before that date. Certain substances that have a history of food use (specifically, those that “have been present in the food supply as an article used for food in a form in which the food has not been chemically altered”) are exempt from the notification requirement. The firm is responsible for ensuring that its product complies with applicable U.S. law.
- The notification must contain the information that is the basis on which a firm has concluded that a dietary supplement containing the new dietary ingredient is reasonably expected to be safe. The firm is responsible for determining what information provides the basis for its decision; at this time, FDA has not published guidance on the specific information that the submission should contain. More information on new dietary ingredients can be found at <http://www.cfsan.fda.gov/~dms/ds-ingrd.html> .
- An exporter should direct any specific inquiries regarding whether a supplement contains “new dietary ingredients” subject to the notification requirement to the FDA using the contact information below:

Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling, and Dietary Supplements
(HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD, 20740-3835
www.cfsan.fda.gov/~dms/supplmnt.html

- According to U.S. Census Statistics, from January - November of 2005 caffeine and ITS salt supplements, Harmonized System Number 293930, valued at approximately USD \$15.9 million were imported from China into the United States.

Intellectual Property Department
Hong Kong SAR Government
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