

Update on Vitamins and Health Food Supplements

Your Global Business Partner

11/25/2003

Courtesy of the U.S. Commercial Service in Spain
A Pilot Partnership between the U.S. Commercial Service
and the State of California Trade Partners

Tel. (34) 91 5648976 • Fax. (34) 91 5630859

www.buyusa.com
madrid.office.box@mail.gov

Update on Vitamins and Health Food Supplements. Spain maintains its strict Policy

International Market Insight [IMI]

ID: 122006

Regions:

EUR Europe Western Europe European Union



Countries:

Spain

Divisions: [Autonomous Community]

Andalucia	Aragon	Asturias	Baleares (Balearic Islands)	Canarias (Canary Islands)
Cantabria	Castilla y Leon	Castilla-La Mancha	Cataluna	Comunidad Valencian
Extremadura	Galicia	La Rioja	Madrid	Murcia
Navarra	Pais Vasco (Basque Country)			

Industry: **Health Technologies**
Sector: **Drugs/Pharmaceuticals**

by: **Jose Ramon Posada/Alicia Mejia**
approver: **Nicholas R. Kuchova**

Report Date: **11/25/2003**
Expires: **11/01/2005**

INTERNATIONAL COPYRIGHT, U.S. & FOREIGN COMMERCIAL SERVICE AND U.S. DEPARTMENT OF STATE, 2004. ALL RIGHTS RESERVED OUTSIDE OF THE UNITED STATES.

Spain has been one of the most restrictive countries in the EU with respect to the use of vitamins and health food products. Since March 2002, Ministry of Health inspectors have raided health food shops and removed 227 different types of health food products from the market. Although the EU parliament has passed a new EU directive on dietetics, Spain maintains its restrictive policy with regard to limits in vitamin and mineral composition.

Summary:

Spain has been one of the most restrictive countries in the EU with respect to the use of vitamins and health food products. Since March 2002, Ministry of Health inspectors have raided health food shops and removed 227 different types of health food products from the market. Although the EU Parliament has passed a new EU directive on dietetics, Spain maintains its restrictive policy with regard to limits in vitamin and mineral composition. (End of Summary).

In Spain, the Ministry of Health must review all vitamins, health food supplements and natural products to determine if the vitamin and mineral content exceeds what Spanish law allows. The Ministry must determine if these vitamins, health food supplements and natural products contain enzymes, amino-acids or hormones. It must also check the vitamin and mineral content, which is very restricted by current Spanish law. If the vitamins and/or supplements surpass the required limits, they may be classified as drugs. In addition, the Ministry of Health must also review all labeling on health food supplements that claim to prevent or cure human disease as Spanish law forbids such claims.

In October 2003, Spain passed a decree in compliance with the June 2002 European Union's Food Supplements Directive. This directive allows for more flexibility than the previous conditions in Spain with regards to the type of substance, value limits, and labeling and advertising requirements. The EU Directive provides a list of substances and formulations that may be

offered for sale within the EU, but has not set a deadline for when these limits are to be decided. Until EU levels are established, which could take up to 7 years, current Spanish regulation will continue; the Spanish decree of October 13, 2003 sets limits for the vitamin and mineral content of nutritional supplements. Limits for herbal extracts and other nourishments will be determined in the future. Following is a list of the vitamins and minerals authorized in the making of food supplements and their recommended daily amount:

1. Vitamins

Vitamin A (Retinol) mg	800	
Vitamin D (Ergocalciferol or colecalcifero) mg	5	
Vitamin E (Tocoferol) mg	10	
Vitamin K (mg)	To be determined	
Vitamin C (Ascorbic Acid) mg	60	
Vitamin B ₁ (Thiamin) mg	1.4	
Vitamin B ₂ (Riboflavin) mg	1.6	
Vitamin B ₃ (Niacin) mg	18	
Vitamin B ₆ (Piridoxina or piridoxal or piridoxamina) mg	2	
Vitamin B ₉ (Folic Acid or folatos) mg	200	
Vitamin B ₁₂ (Cianocobalamina) mg		1
Biotin (mg)		0.15
Pantothenic Acid (mg)		6

2. Minerals

Sodium (mg)	To be determined
Chlorine (mg)	To be determined
Potassium (mg)	To be determined
Calcium (mg)	800
Phosphorous (mg)	800
Magnesium (mg)	300
Iron (mg)	14
Zinc (mg)	15
Manganese (mg)	To be determined
Copper (mg)	To be determined
Iodine (mg)	150
Selenium (mg)	To be determined
Molybdenum (mg)	To be determined
Chromium (mg)	To be determined
Fluorine (mg)	To be determined

Some Spanish companies have tried recently to take advantage of the projected EU Directive and started selling new health food products. The Ministry of Health reacted harshly against this market strategy and, since March 2002, have identified and ordered the removal of 227 products sold in health food stores throughout Spain. Many of the products removed claimed preventative or curative properties.

The approach to selling vitamins and health supplements in Spain is very different than in the United States. Vitamins and supplements commonly found in U.S. health food stores are still considered drugs by the Spanish Ministry of Health and restricted in terms of sale. The importation of drugs is much more restricted than the importation of health foods--it requires a registration process that may take several months to years, depending on how the substance is

classified by the Ministry (i.e. prescriptive or over the counter). U.S. companies wishing to export vitamins and health food products to Spain must provide the Spanish Ministry of Health with technical data on the products' composition and meet labeling requirements.

CS Spain recommends that U.S. companies interested in the Spanish market and the EU in general study the new EU Directive in order to forge a suitable strategy for selling in Spain. We also recommend reading the IMI: Regulation of the Food Supplements Market: European Union, which can be found in the USA Trade Database.

The EU is contemplating the development of another directive with a much less restrictive approach to the sale of vitamin, mineral, herbal extracts, etc., but until this directive is developed, individual member states will continue to regulate health food products. The Spanish market is practically closed to those products whose composition exceeds the limits outlined in this report.

For additional information, please contact:

Jose Ramon Posada, Commercial Specialist
Tel: 34 91 564 8976, ext. 2605
Fax: 34 91 563 859
E-mail: jose.posada@mail.doc.gov

For additional information regarding market research specific to your products and services, ask about our **Flexible Market Research** and **Customized Market Analysis** programs by contacting us at **1-800-USA-TRAD(E)** or www.export.gov or www.buyusa.com. Both reports provide timely, customized, reliable answers to your inquiries about a market and its receptivity to your products and services.

To the best of our knowledge, the information contained in this report is accurate as of the date published. However, **The Department of Commerce** does not take responsibility for actions readers may take based on the information contained herein. Readers should always conduct their own due diligence before entering into business ventures or other commercial arrangements. **The Department of Commerce** can assist companies in these endeavors.

close window

print