

Committee on Sanitary and Phytosanitary Measures

NOTIFICATION

1.	<b>Member to Agreement notifying:</b> <u>UNITED STATES</u> <b>If applicable, name of local government involved:</b>
2.	<b>Agency responsible:</b> Food and Drug Administration
3.	<b>Products covered (tariff item number(s) as specified in national schedules deposited with the WTO. ICS numbers may be provided in addition, where applicable):</b> Medical foods
4.	<b>Title and number of pages of the notified document:</b> Regulation of Medical Foods (11 pages)
5.	<b>Description of content:</b> The Food and Drug Administration (FDA) has published an advance notice of proposed rulemaking and is soliciting comments to initiate a reevaluation of its approach to the regulation of the Broad Group of Heterogeneous Products that are marketed as medical foods. FDA's goal is to arrive at a regulatory regime that will ensure that: these products are safe for their intended uses, especially because they are likely to be the sole or a major source of nutrients for sick and otherwise vulnerable people; claims for these products are truthful, not misleading and supported by sound science; and the labelling of these products is adequate to inform consumers about how to use them in a safe and appropriate manner. The Agency believes that there is a need to reevaluate its policy for regulating medical foods because of a number of developments, including enactment of a statutory definition of "medical food," the rapid increase in the variety and number of products that are marketed as medical foods, safety problems associated with the manufacture and quality control of these products, and the potential for fraud as claims that are not supported by sound science proliferate for these products.
6.	<b>Objective and rationale:</b> Human health
7.	<b>An international standard, guideline or recommendation does not exist [ X ].</b> <b>If an international standard, guideline or recommendation exists, whenever possible, identify deviations:</b>
8.	<b>Relevant documents and language(s) in which these are available:</b> 61 FR 60661, 29 November 1996; 21 CFR CH.1; available in English
9.	<b>Proposed date of adoption:</b> To be determined.

10.	<b>Proposed date of entry into force:</b> The date of entry into force will be announced when the final rule is published in the Federal Register.
11.	<b>Final date for comments:</b> 27 February 1997  <b>Agency or authority designated to handle comments:</b> Food and Drug Administration
12.	<b>Texts available from: National enquiry point [ X ] or address, telefax number and E-mail address (if available) of other body:</b>  USDA/FAS/OFSTS Attn: Carolyn F. Wilson Room 5545 South Agriculture Building 14th and Independence Washington, D.C. 20250 Tel: (202) 720 22 39 Fax: (202) 690 06 77 E-mail address: wilsonc@fas.usda.gov