

WORLD TRADE ORGANIZATION

G/TBT/N/USA/86
23 November 2004

(04-5100)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (90) Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Human Drug Products (HS Chapter 3003) (ICS 11.120)
5.	Title, number of pages and language(s) of the notified document: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Monograph for Over-the-Counter Nasal Decongestant Drug Products (8 pages, in English)
6.	Description of content: The Food and Drug Administration (FDA) is proposing to amend the final monograph (FM) for over-the-counter (OTC) nasal decongestant drug products (drug products used to relieve nasal congestion due to a cold, hay fever, or other upper respiratory allergies) to add phenylephrine bitartrate as generally recognized as safe and effective (GRASE) when used in an effervescent tablet. An effervescent tablet is intended to be dissolved in water before taking by mouth. This proposal is part of FDA's ongoing review of OTC drug products.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health
8.	Relevant documents: 69 Federal Register (FR) 63482 2 November 2004; Title 21 Code of Federal Regulations (CFR) Part 341. Will appear in the Federal Register when adopted.
9.	Proposed date of adoption: Proposed date of entry into force: } To be determined
10.	Final date for comments: 31 January 2005

- 11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:**

Full text of this Notification is now available on the Internet at URLs:

<http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-24423.htm>

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