

WORLD TRADE ORGANIZATION

G/TBT/N/USA/67
19 July 2004

(04-3076)

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 (72) 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): Cosmetics and Human Food (HS Chapters 33 and 2106) (ICS 67.020 and 71.100)
5. Title, number of pages and language(s) of the notified document: Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle (10 pages, in English)
6. Description of content: The Food and Drug Administration (FDA) is proposing to require that manufacturers and processors of human food and cosmetics that are manufactured from, processed with, or otherwise contain, material from cattle must establish and maintain records sufficient to demonstrate the food or cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials. This is a companion rulemaking to FDA's interim final rule entitled "Use of Materials Derived From Cattle in Human Food and Cosmetics," published in this issue of the Federal Register. FDA is proposing recordkeeping requirements because records documenting the absence of prohibited cattle materials are needed by manufacturers and processors of human food and cosmetics that contain cattle material to ensure that these products do not contain prohibited cattle materials. In addition, such records are necessary to help FDA ensure compliance with the requirements of the interim final rule.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health.
8. Relevant documents: 69 Federal Register (FR) 42275 14 July 2004; Title 21 Code of Federal Regulations (CFR) Parts 189, and 700. Will appear in the Federal Register when adopted.
9. Proposed date of adoption: ? Proposed date of entry into force: ? To be determined

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10. Final date for comments: 13 August 2004

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

Available on the Internet at URLs:

<http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-15880.htm>

<http://a257.g.akamaitech.net/7/257/2422/14mar20010800/edocket.access.gpo.gov/2004/pdf/04-15880.pdf>