

# WORLD TRADE ORGANIZATION

G/TBT/N/USA/241

1 March 2007

(07-0881)

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

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

<b>1. Member to Agreement notifying:</b> <u>UNITED STATES</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) (248) <b>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:</b>
<b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Insect repellent - sunscreen drug products (HS: 3304, 3808; ICS: 13.120, 65.100, 71.100)
<b>5. Title, number of pages and language(s) of the notified document:</b> Insect Repellent-Sunscreen Drug Products for Over-the-Counter Human Use (4 pages, in English)
<b>6. Description of content:</b> The Food and Drug Administration (FDA) is seeking information to formulate a regulatory position on insect repellent products that contain over-the-counter (OTC) sunscreen ingredients. FDA is considering amending its monograph for OTC sunscreen drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded) to add conditions for marketing insect repellent-sunscreen drug products. The insect repellent ingredients in these products are regulated by the Environmental Protection Agency (EPA). Elsewhere in this issue of the Federal Register is a companion document in which EPA is also requesting information and comments on these products. The decision on what regulations, if any, to propose will be based, in part, on information and comments submitted in response to this request for data and information.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human life and health
<b>8. Relevant documents:</b> 72 Federal Register (FR) 7941 22 February 2007; Title 21 Code of Federal Regulations (CFR) Part 352. Will appear in the Federal Register when adopted
<b>9. Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> } To be determined
<b>10. Final date for comments:</b> 23 May 2007

**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:**

Internet URLs:

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/E7-2890.htm>

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/E7-2890.pdf>