

# WORLD TRADE ORGANIZATION

G/SPS/N/USA/346  
23 October 2000

(00-4379)

Committee on Sanitary and Phytosanitary Measures

Original: English

## 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> US Food and Drug Administration
3.	<b>Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers may be provided in addition, where applicable). Regions or countries likely to be affected, to the extent relevant or practicable:</b> Veterinary medicinal products
4.	<b>Title and number of pages of the notified document:</b> International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19); Availability; Request for Comments (2 pages plus guidance documents)
5.	<b>Description of content:</b> The Food and Drug Administration (FDA) is announcing the availability for comment of three draft guidances for industry (Nos.109, 110, and 111, respectively) entitled: "Effectiveness of Anthelmintics: Specific Recommendations for Equine" (VICH GL15), "Effectiveness of Anthelmintics: Specific Recommendations for Porcine" (VICH GL16), and "Effectiveness of Anthelmintics: Specific Recommendations for Canine" (VICH GL19). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan, and the United States.
6.	<b>Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests
7.	<b>An international standard, guideline or recommendation does not exist</b> <input checked="" type="checkbox"/> . <b>If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:</b>
8.	<b>Relevant documents and language(s) in which these are available:</b> 65 FR 62723, 19 October 2000 (Available in English)
9.	<b>Proposed date of adoption:</b> Will be published as future guidance.

<b>10.</b>	<b>Proposed date of entry into force:</b> Same as paragraph 9
<b>11.</b>	<b>Final date for comments:</b> 18 December 2000 <b>Agency or authority designated to handle comments:</b> Food and Drug Administration <b>[ ] National notification authority, [ ] National enquiry point, or address, fax number and E-mail address (if available) of other body:</b> Detailed instruction on where and how to send comments is in the body of the full text - which will be sent upon request to the address in paragraph 12.
<b>12.</b>	<b>Texts available from: [ X ] National notification authority, [ X ] National enquiry point or address, fax number and E-mail address (if available) of other body:</b>  United States SPS Enquiry Point/Notification Authority USDA/FAS/FSTSD ATTN: Carolyn F. Wilson Room 5545 South Agriculture Building Stop 1027 1400 Independence Avenue, S.W. Washington, D.C. 20250 Phone (202) 720-2239 Fax (202) 690-0677 E-mail Address: ofsts@fas.usda.gov