

WORLD TRADE ORGANIZATION

G/SPS/N/USA/370
20 December 2000

(00-5566)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved:
2.	Agency responsible: US Food and Drug Administration - FDA
3.	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: Veterinary medicinal products
4.	Title and number of pages of the notified document: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22); Availability; Request for Comments (2 pages plus draft guidance)
5.	Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry (#115) entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Studies" (VICH GL22). This draft guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This draft VICH guidance document recommends a basic battery of tests that can be used to evaluate the reproduction safety of veterinary drug residues in human food. This draft guidance is intended to provide harmonized guidance on the core recommendation for a multigeneration study for the safety evaluation of veterinary drug residues in human food. The current draft guidance is one of a series of guidances developed to facilitate the mutual acceptance of safety data necessary for the determination of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the safety evaluation of veterinary residues in human food (VICH Guidance on General Testing Approach) will be made available at a later time. VICH GL22 was developed after consideration of the existing ICH guidance for pharmaceuticals for human use on "Detection of Toxicity to Reproduction for Medicinal Products" and its addendum, "Toxicity to Male Fertility" in conjunction with the current practices for evaluating veterinary drug residues in human food in the European Union, Japan, the United States, Australia, and New Zealand.

6.	Objective and rationale: <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.	An international standard, guideline or recommendation does not exist <input checked="" type="checkbox"/> . If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:
8.	Relevant documents and language(s) in which these are available: 65 FR 79373, 19 December 2000 (Available in English)
9.	Proposed date of adoption: Will be published as future guidance.
10.	Proposed date of entry into force: Same as paragraph 9.
11.	Final date for comments: 20 February 2001 Agency or authority designated to handle comments: US Food and Drug Administration [] National notification authority, [] National enquiry point, or address, fax number and E-mail address (if available) of other body: 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.
12.	Texts available from: <input checked="" type="checkbox"/> National notification authority, <input checked="" type="checkbox"/> National enquiry point or address, fax number and E-mail address (if available) of other body: 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: ofsts@fas.usda.gov