

# WORLD TRADE ORGANIZATION

G/SPS/N/USA/180

18 August 1999

(99-3474)

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> U.S. 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Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on VICH GL9 Good Clinical Practices; Request for Comments (2 pages, plus the guidance document).
5.	<b>Description of content:</b> The Food and Drug Administration (FDA) is announcing the availability for comment of the following draft guidance document entitled: VICH GL9 "Good Clinical Practices". This draft guidance document was developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). It is intended to provide a unified standard for designing, conducting, monitoring, recording, and reporting studies used in registration applications for approval of veterinary products submitted 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> 64 FR 42135, 3 August 1999; Available in English
9.	<b>Proposed date of adoption:</b> Will be published as future guidance.
10.	<b>Proposed date of entry into force:</b> Will be published as future guidance.

- 11. Final date for comments:** 2 September 1999  
**Agency or authority designated to handle comments:** [ ] National notification authority, [ ] National enquiry point, or address, fax number and E-mail address (if available) of other body: Food and Drug Administration

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:** [ X ] National notification authority, [ X ] 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/FSTD  
Attn: Carolyn F. Wilson  
Room 5545 South Agriculture Building  
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