WORLD TRADE ORGANIZATION

G/SPS/N/USA/370/Add.1
14 January 2002

(02-0155)

Committee on Sanitary and Phytosanitary Measures Original: English

NOTIFICATION

Addendum

The following communication by the United States is being circulated:

International Cooperation on Harmonization of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidance on "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22); Availability

The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#115) entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing" (VICH GL22). This final guidance has been adapted for veterinary use by the International Cooperation on Harmonization 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 Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). This final 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.

Submit written or electronic comments at any time. Comments should be submitted through your own VICH representative.

The full text of this addendum (notice of final guidance) is available from the address below. The text includes instructions for obtaining copies of the final guidance and for submitting comments.

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
Tel: (202) 720-2239
Fax: (202) 690-0677
E-mail: ofsts@fas.usda.gov
