

# WORLD TRADE ORGANIZATION

G/SPS/N/USA/152

31 March 1999

(99-1316)

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> Department of Agriculture, Animal and Plant Health Inspection Service
3.	<b>Products covered (tariff item number(s) as specified in national schedules deposited with the WTO. ICS numbers may be provided in addition, where applicable):</b> Veterinary biological products
4.	<b>Title and number of pages of the notified document:</b> Viruses, Serums, Toxins, and Analogous Products; Packaging and Labelling
5.	<b>Description of content:</b> <p>The Animal and Plant Health Inspection Service (APHIS) is proposing to amend the regulations concerning packaging and labelling of veterinary biological products by requiring the Animal and Plant Health Inspection Service product code number as well as an appropriate consumer contact telephone number to appear on labelling. The amendments would also clarify label requirements with respect to overshadowing the true name of the product and requirements for products shipped to a foreign country. In addition, this proposal contains label requirements concerning minimum age for product administration and the potential for maternal antibody interference. The effect of the proposed rule would be to update the regulations by providing additional information to users of veterinary biologics and to make regulatory labelling provisions more consistent with current practices.</p>
6.	<b>Objective and rationale:</b> Animal health
7.	<b>An international standard, guideline or recommendation does not exist [ X ].</b> <b>If an international standard, guideline or recommendation exists, whenever possible, identify deviations:</b>
8.	<b>Relevant documents and language(s) in which these are available:</b> 64 FR 13365, 18 March 1999 (available in English, 4 pages); 9 CFR Part 112
9.	<b>Proposed date of adoption:</b> To be determined.
10.	<b>Proposed date of entry into force:</b> The date of entry into force will be announced when the final rule is published in the Federal Register.

**11. Final date for comments:** 17 May 1999  
**Agency or authority designated to handle comments:** Animal and Plant Health Inspection Service, USDA

**12. Texts available from: National enquiry point [ X ] or address, telefax number and E-mail address (if available) of other body:**

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