

WORLD TRADE ORGANIZATION

G/SPS/N/USA/265

28 April 2000

(00-1711)

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
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: Animal drugs
4.	Title and number of pages of the notified document: Draft Guidance for Industry: The Use of Published Literature in Support of New Animal Drug Approval; Availability (2 pages plus draft guidance)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	Description of content: The Food and Drug Administration (FDA) is announcing the availability for comment of a draft guidance for industry entitled "The Use of Published Literature in Support of New Animal Drug Approval". The draft guidance is intended to fulfill the section of the FDA Modernization Act of 1997 (FDAMA) that requires the agency to issue guidance to clarify the circumstances in which published matter may be the basis for approval of a supplemental application. The draft guidance also clarifies the circumstances in which published literature may be the basis for approval of an original application. The draft guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approval.
6.	Objective and rationale: [X] food safety, [X] animal health, [] plant protection, [] protect humans from animal/plant pest or disease, [] protect territory from other damage from pests
7.	An international standard, guideline or recommendation does not exist [X]. 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 20997, 19 April 2000 (Available in English)
9.	Proposed date of adoption: The agency has developed this draft guidance in accordance with the agency's good guidance practices.
10.	Proposed date of entry into force: Same as above

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| <p>11. Final date for comments: 18 July 2000.
Agency or authority designated to handle comments: 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.</p> |
| <p>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:</p> <p>United States SPS Enquiry Point/Notification Authority
USDA/FAS/FSTSD
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