

WORLD TRADE ORGANIZATION

G/SPS/N/USA/357
5 December 2000

(00-5239)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 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: New Animal Drugs for Use in Animal Feeds; Salinomycin and Bacitracin Methylene Disalicylate (2 pages) |
| 5. | <p>Description of content: The Food and Drug Administration (FDA) is announcing an amendment to the animal drug regulations to reflect approval of a new animal drug application (NADA). The NADA provides for use of approved, single-ingredient salinomycin and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds for broiler, roaster, and replacement (breeder and layer) chickens. The Type C medicated feeds are used for prevention of coccidiosis and as an aid in the prevention and control of necrotic enteritis in broiler, roaster, and replacement (breeder and layer) chickens; and for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in roaster and replacement (breeder and layer) chickens. Previously established acceptable daily intakes (ADI's) for total residues of bacitracin and salinomycin are also being codified.</p> <p>21 CFR - Section 556.70 is revised to read as follows:</p> <p>Sec. 556.70 Bacitracin.</p> <p>(a) Acceptable daily intake (ADI). The ADI for total residues of bacitracin is 0.05 milligram per kilogram of body weight per day.</p> <p>(b) Tolerances. The tolerance for residues of bacitracin from zinc bacitracin or bacitracin methylene disalicylate in uncooked edible tissues of cattle, swine, chickens, turkeys, pheasants, and quail, and in milk and eggs is 0.5 part per million.</p> <p>Section 556.592 is added to subpart B to read as follows:</p> <p>Sec. 556.592 Salinomycin.</p> <p>(a) Acceptable daily intake (ADI). The ADI for total residues of salinomycin is 0.005 milligram per kilogram of body weight per day.</p> <p>(b) [Reserved]</p> |

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| 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 70790, 28 November 2000 (Available in English) |
| 9. | Proposed date of adoption: 28 November 2000 |
| 10. | Proposed date of entry into force: 28 November 2000 |
| 11. | Final date for comments: 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: The full text of this announcement 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 Address: ofsts@fas.usda.gov |