



16 April 2014

(14-2378)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>UNITED STATES OF AMERICA</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> US Food and Drug Administration
<b>3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> Animal feeds
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> New Animal Drugs for Use in Animal Feeds; Withdrawal of Approval of New Animal Drug Applications; Bambermycins; Hygromycin B; Lincomycin; Pyrantel; Tylosin; Tylosin and Sulfamethazine; Virginiamycin <b>Language(s):</b> English <b>Number of pages:</b> 2 <a href="http://www.gpo.gov/fdsys/pkg/FR-2014-04-10/pdf/2014-08011.pdf">http://www.gpo.gov/fdsys/pkg/FR-2014-04-10/pdf/2014-08011.pdf</a>
<b>6. Description of content:</b> The Food and Drug Administration (FDA) is amending its animal drug regulations to reflect the withdrawal of approval of 19 new animal drug applications (NADAs) for certain Type A medicated articles and Type B medicated feeds. This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.
<b>7. 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.
<b>8. Is there a relevant international standard? If so, identify the standard:</b> <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text) <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number) <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number) <input checked="" type="checkbox"/> None <b>Does this proposed regulation conform to the relevant international standard?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, describe, whenever possible, how and why it deviates from the international standard:</b>

<b>9.</b>	<b>Other relevant documents and language(s) in which these are available:</b> Draft Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm; US Food, Drug, and Cosmetic Act, <a href="http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/default.htm">http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCA/default.htm</a> (available in English)
<b>10.</b>	<b>Proposed date of adoption (dd/mm/yy):</b> 21 April 2014 <b>Proposed date of publication (dd/mm/yy):</b> 10 April 2014
<b>11.</b>	<b>Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 21 April 2014 <input type="checkbox"/> Trade facilitating measure
<b>12.</b>	<b>Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable for notice of drug withdrawal. <b>Agency or authority designated to handle comments:</b> <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:  FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, john.bartkowiak@fda.hhs.gov
<b>13.</b>	<b>Texts available from:</b> <input checked="" type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:  United States SPS National Notification Authority, USDA Foreign Agricultural Service, International Regulations and Standards Division (IRSD), Stop 1014, Washington D.C. 20250; Tel: +(1 202) 720 1301; Fax: +(1 202) 720 0433; E-mail: us.spsenquiry@fas.usda.gov