



NOTIFICATION

1.	Notifying Member: <u>UNITED STATES OF AMERICA</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 should be provided in addition, where applicable): Animal feeds
4.	Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	Title of the notified document: 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 Language(s): English Number of pages: 2 http://www.gpo.gov/fdsys/pkg/FR-2014-04-10/pdf/2014-08011.pdf
6.	Description of content: 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.
7.	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.
8.	Is there a relevant international standard? If so, identify the standard: <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 Does this proposed regulation conform to the relevant international standard? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, describe, whenever possible, how and why it deviates from the international standard:

9.	<p>Other relevant documents and language(s) in which these are available: 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, http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct/FDCAct/default.htm (available in English)</p>
10.	<p>Proposed date of adoption (dd/mm/yy): 21 April 2014 Proposed date of publication (dd/mm/yy): 10 April 2014</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 21 April 2014 <input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <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. Agency or authority designated to handle comments: <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</p>
13.	<p>Texts available from: <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</p>