



17 July 2014

(14-4158)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

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 (FDA)
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): Certain types of medicated animal feed
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: Withdrawal of Approval of Part of a New Animal Drug Application; Procaine Penicillin Language(s): English Number of pages: 2
6. Description of content: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a three-way, fixed-ratio, combination drug Type A medicated article that pertain to use of the procaine penicillin component for growth promotion indications in swine. This action is being taken at the sponsor's request because the three-way Type A medicated article is no longer manufactured.
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.	Other relevant documents and language(s) in which these are available: FDA Guidance for Industry #209: "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf (available in English)
10.	Proposed date of adoption (dd/mm/yy): 2 July 2014 Proposed date of publication (dd/mm/yy): 2 July 2014
11.	Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 2 July 2014 <input type="checkbox"/> Trade facilitating measure
12.	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 withdrawal of approval for animal drug. Agency or authority designated to handle comments: <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
13.	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