Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 03–109–2]

Imported Fire Ant; Additions to Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the imported fire ant regulations by designating as quarantined areas all or portions of 20 counties in North Carolina and restricting the interstate movement of regulated articles from those areas. The interim rule was necessary to prevent the artificial spread of the imported fire ant to noninfested areas of the United States.

EFFECTIVE DATE: The interim rule became effective on April 29, 2004

FOR FURTHER INFORMATION CONTACT: Mr. Charles L. Brown, Imported Fire Ant Quarantine Program Manager, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1231; (301) 734–8247.

SUPPLEMENTARY INFORMATION:

Background

The imported fire ant regulations (contained in 7 CFR 301.81 through 7 CFR 301.81–10 and referred to below as the regulations) quarantine infested States or infested areas within States and restrict the interstate movement of regulated articles to prevent the artificial spread of the imported fire ant.

In an interim rule effective and published in the **Federal Register** on April 29, 2004 (69 FR 23415–23417, Docket No. 03–109–1), we amended the regulations in § 301.81–3(e) by designating as quarantined areas all or portions of 20 counties in North Carolina.

Comments on the interim rule were required to be received on or before June 28, 2004. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 301—DOMESTIC QUARANTINE NOTICES

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 69 FR 23415–23417 on April 29, 2004.

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 19th day of July 2004.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04–16816 Filed 7–22–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The NADA provides for veterinary prescription use of ceftiofur crystalline free acid suspension in swine, by intramuscular injection, for the treatment of swine respiratory disease (SRD).

DATES: This rule is effective July 23, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed NADA 141–235 for EXCEDE (ceftiofur crystalline free acid) for Swine Sterile Suspension. The NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in swine, by intramuscular injection, for the treatment of SRD associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. The application is approved as June 18, 2004, and the regulations are amended in 21 CFR 522.315 and 556.113 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning June 18, 2004.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on