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]

BILLING CODE 3410–34–P

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

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule''in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.315 is amended by revising paragraphs (a) and (d) to read as follows:

§ 522.315 Ceftiofur crystalline free acid.

(a) *Specifications*—(1) Each milliliter (mL) of suspension contains 100 milligrams (mg) ceftiofur equivalents (CE).

(2) Each mL of suspension contains 200 mg CE.

* * * * *

(d) *Conditions of use*—(1) *Swine.* The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount.* 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis.*

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Following label use as a single treatment, a 14-day preslaughter withdrawal period is required.

(2) *Cattle.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* 6.6 mg CE per kg of body weight by a single, subcutaneous injection in the middle third of the posterior aspect of the ear.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD), shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus.*

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. Section 556.113 is amended in paragraph (b)(1) by removing ''*Swine*, *poultry*,'' and by adding in its place ''*Poultry*''; by redesignating paragraph (b)(2) as paragraph (b)(3); by adding new paragraph (b)(2); and by revising newly redesignated paragraph (b)(3) to read as follows:

§ 556.113 Ceftiofur.

* * * * *

(b) * * *

(2) *Swine.* The tolerances for desfuroylceftiofur (marker residue) are:

(i) *Kidney (target tissue).* 0.25 parts per million (ppm).

(ii)*Liver.* 3 ppm.

(iii) *Muscle.* 2 ppm.

(3) *Cattle.* The tolerances for desfuroylceftiofur (marker residue) are:

(i) *Kidney (target tissue).* 8 ppm.

(ii) *Liver.* 2 ppm.

(iii)*Muscle.* 1 ppm.

(iv) *Injection site muscle.* 166 ppm.

(v) *Milk.* 0.1 ppm.

Dated: July 13, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–16760 Filed 7–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

28 CFR Part 25

[FBI 108F; AG Order No. 2727–2004]

RIN 1110–AA07

National Instant Criminal Background Check System Regulation

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice (''the Department'') is publishing a final rule amending the regulations implementing the National Instant Criminal Background Check System (''NICS'') pursuant to the Brady Handgun Violence Prevention Act (''Brady Act'').

EFFECTIVE DATES: The effective date for the final rule is July 20, 2004.

FOR FURTHER INFORMATION CONTACT: Eugene Donaldson, Federal Bureau of Investigation, National Instant Criminal Background Check System (NICS) Section, Module A–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306–0147, (304) 625–3500.

SUPPLEMENTARY INFORMATION: This notice finalizes the rule proposed in the **Federal Register** on July 6, 2001 (66 FR 35567). The Federal Bureau of Investigation (''FBI'') accepted comments on the proposed rule from interested parties until October 22, 2001, and 1,164 comments were received. With the exception of certain changes explained below, the proposed rule is adopted as final.

Significant Comments or Changes:

The Department on July 6, 2001, published a notice of five proposals for changes in the regulations governing the NICS. The changes relate to the amount of time that the NICS retains information about approved firearm transfers in the system's chronological log of background check transactions (''Audit Log'') and the manner in which that information may be used to audit the use and performance of the NICS. The proposed changes sought to balance the Brady Act's mandate that the Department protect legitimate privacy interests of law-abiding firearm transferees and the Department's obligation to enforce the Brady Act and the rest of the Gun Control Act and prevent prohibited persons from receiving firearms.

The comments about each of the five proposals are addressed below.