DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate Sodium Injection

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 a supplemental new animal drug application (NADA) filed by Bayer HealthCare LLC. The supplemental NADA provides for veterinary prescription use of a hyaluronate sodium solution, formulated with a benzyl alcohol preservative, for intravenous administration to horses for the treatment of osteoarthritis.

DATES: This rule is effective January 11, 2006.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 140–883 that provides for veterinary prescription use of LEGEND Multi-dose (hyaluronate sodium) Injectable Solution. The supplemental NADA provides for use of this hyaluronate sodium solution, formulated with a benzyl alcohol preservative, from a multi-dose vial for intravenous administration to horses for the treatment of carpal or fetlock osteoarthritis. The supplemental NADA is approved as of December 15, 2005, and the regulations are amended in 21 CFR 522.1145 to reflect the approval and a current format. 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.

The agency has determined under 21 CFR 25.33(d)(1) 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 Subject in 21 CFR Part 522

Animal drugs.

■ 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 part 522 is 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 522.1145 is amended by revising paragraph (e) to read as follows:

§ 522.1145 Hyaluronate sodium injection.

* * * * *

(e)(1) *Specifications*. Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

(2) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use in horses*—(i) *Amount*. 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: January 4, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 06–229 Filed 1–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin

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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for use of monensin Type C medicated feeds in component feeding systems (including top dress) for increased milk production efficiency in dairy cows.

DATES: This rule is effective January 11, 2006.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for the use of RUMENSIN 80 (monensin sodium) Type A medicated article in Type C medicated feeds fed in component feeding systems (including top dress) used for increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows. The supplemental NADA is approved as of December 15, 2005, and the regulations in 21 CFR 558.355 are amended 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.

FDA has determined under 21 CFR 25.33(a)(1) 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 in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. Section 558.355 is amended in the last sentence in paragraph (f)(3)(xiii)(B) by removing ''(d)(12)'' and adding in its place ''(d)(13)''; and by adding paragraph (f)(3)(xiv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(xiv) *Amount per ton.* Monensin, 11 to 400 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See paragraphs (d)(2), (d)(5), (d)(6), (d)(7)(i), (d)(7)(ii), (d)(7)(iii), (d)(7)(vi), (d)(8), and (d)(13) of this section.

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Dated: January 4, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 06–228 Filed 1–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

28 CFR Part 105

[Docket No. FBI 112; AG Order No. 2796–2006]

RIN 1110–AA23

Implementation of the Private Security Officer Employment Authorization Act of 2004

AGENCY: Federal Bureau of Investigation (FBI), Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of Justice (the Department) hereby amends title 28 of the Code of Federal Regulations to authorize access to FBI-maintained criminal justice information systems to effectuate the Private Security Officer Employment Authorization Act of 2004, which was enacted as section 6402 of the Intelligence Reform and Terrorism Prevention Act of 2004. This law authorizes a fingerprint-based check of state and national criminal history records to screen prospective and current private security officers and requires the Attorney General to issue rules to regulate the ''security, confidentiality, accuracy, use, submission, dissemination, destruction of information and audits, and record keeping'' of the criminal history record information (CHRI) and related information; standards for qualifying as an authorized employer; and the imposition of fees.

DATES: The rule is effective January 11, 2006. Written comments must be received on or before March 13, 2006.

ADDRESSES: All comments may be submitted to Assistant General Counsel Harold M. Sklar, Federal Bureau of Investigation, CJIS Division, 1000 Custer Hollow Road, Module E–3, Clarksburg, West Virginia 26306, or by telefacsimile to (304) 625–3944. To ensure proper handling, please reference FBI Docket No. 112 on your correspondence. You may view an electronic version of this proposed rule at *http://www.regulations.gov.* You may also comment via electronic mail at *enexreg@leo.gov* or by using the *http://www.regulations.gov* comment form for this regulation. When submitting comments electronically you must include RIN 1110-AA23 or FBI Docket No 112 in the subject box.

FOR FURTHER INFORMATION CONTACT: Assistant General Counsel Harold M. Sklar, telephone number (304) 625–2000.

SUPPLEMENTARY INFORMATION:

Background

On December 17, 2004, the Intelligence Reform and Terrorism Prevention Act of 2004, Public Law 108–458, became law. Section 6402 of that Act (The Private Security Officer Employment Authorization Act of 2004) authorizes a fingerprint-based criminal history check of state and national criminal history records to screen prospective and current private security officers. Section 6402(d)(2) requires the Attorney General to publish an interim final or final regulation within 180 days of the statute's enactment to regulate the ''security, confidentiality, accuracy, use, submission, dissemination, destruction of information and audits, and record keeping'' of the CHRI and related information; standards for qualifying an authorized employer; and the imposition of fees.

The FBI maintains several criminal justice information systems, notably the Fingerprint Identification Record System (FIRS) and the National Crime Information Center (NCIC). Access to the FIRS is predicated upon fingerprint submission through the Integrated Automated Fingerprint Identification System (IAFIS). Previously enacted federal law authorizes similar criminal history record checks for persons engaged in other professions and occupations, such as the banking, securities, and nursing home industries. In implementing section 6402, the interim rule seeks to ensure that the exchange of CHRI and related information relating to the employment of private security guards is accomplished as fully and effectively as possible, achieving the public safety goals of section 6402 and recognizing the sensitive nature of the information involved. To that end, the Department is amending title 28 of the Code of Federal Regulations (CFR) to regulate the exchange of CHRI authorized by section 6402.

Additional Information

The following discussion provides additional information to participating States, authorized employers, and prospective and current private security officers on the operation of the interim rule.

a. To initiate a criminal history record check, section 6402(d)(1)(A) requires the submission of ''fingerprints or other means of positive identification * * *.'' The IAFIS presently utilizes ten rolled fingerprints (captured or submitted manually or electronically) to effectuate a search of the FBI's criminal history repository. Effective June 15, 2005,