

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Board's meetings were widely publicized throughout the potato industry and all interested persons were invited to attend the meetings and participate in Board deliberations. Like all Board meetings, the March 18, 2006, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue. Finally, interested persons are invited to submit information on the regulatory and informational impacts of this action on small businesses.

This rule invites comments on a change to the Administrative Committee structure as currently prescribed under the Plan. Any comments timely received will be considered prior to finalization of this rule.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Making this change effective prior to that date will facilitate Committee operations; (2) this issue has been widely discussed at various industry and association meetings, and interested persons have had time to determine and express their positions; and (3) this rule provides a 60-day comment period and any comments received will be considered prior to finalization of this rule.

#### List of Subjects in 7 CFR Part 1207

Advertising, Agricultural research, Imports, Potatoes, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 1207 is amended as follows:

#### PART 1207—POTATO RESEARCH AND PROMOTION PLAN

■ 1. The authority citation for 7 CFR part 1207 continues to read as follows:

**Authority:** 7 U.S.C. 2611–2627.

■ 2. Section 1207.507(a) is revised to read as follows:

#### § 1207.507 Administrative Committee.

(a) The Board shall annually select from among its members an Administrative Committee composed of producer members as provided for in the Board's bylaws, one or more importer members, and the public member. Selection shall be made in such manner as the Board may prescribe: Except that such committee shall include the Chairperson and seven Vice-Chairpersons, one of whom shall also serve as the Secretary and Treasurer of the Board.

\* \* \* \* \*

Dated: December 18, 2006.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E6–21911 Filed 12–21–06; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin

**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 abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for use of a gentamicin sulfate injectable solution in piglets for treatment of porcine colibacillosis.

**DATES:** This rule is effective December 22, 2006.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: [john.harshman@fda.hhs.gov](mailto:john.harshman@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215, filed ANADA 200–394 for the use of Gentamicin Sulfate Injection in piglets up to 3 days old for treatment of porcine colibacillosis caused by strains of *Escherichia coli* sensitive to gentamicin. Sparhawk Laboratories, Inc.'s Gentamicin Sulfate Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s GARACIN Piglet Injection, approved

under NADA 103–037. The ANADA is approved as of November 17, 2006, and the regulations in 21 CFR 522.1044 are amended 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.

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 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. In § 522.1044, revise the section heading and paragraphs (a) and (b) to read as follows:

#### § 522.1044 Gentamicin.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 5, 50, or 100 milligrams (mg) gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000061 for use of 5 mg per milliliter (/mL) solution in swine as in paragraph (d)(4), 50 mg/mL solution in dogs and cats as in paragraph (d)(1), 50 mg/mL and 100 mg/mL solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 000010 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) No. 059130 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

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Dated: December 13, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E6-21951 Filed 12-21-06; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 812**

[Docket No. 2006N-0494]

**Medical Device Regulations; Disqualification of a Clinical Investigator; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending a medical device regulation to include references to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health is listed in this regulation. This action is being taken to ensure the accuracy of FDA's regulations.

**DATES:** This rule is effective December 22, 2006.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is amending 21 CFR 812.119(a) to include references to CBER and CDER. This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health is listed in this regulation. The appropriate Center that

has regulatory responsibility for the medical device subject to this regulation is responsible for corresponding with the investigator of the study concerning any possible violations of the applicable requirements. Therefore, FDA is updating this regulation to include the references to CBER and CDER.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only a technical change to update references in the Code of Federal Regulations, and is nonsubstantive.

**List of Subjects in 21 CFR Part 812**

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 812 is amended as follows:

**PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

■ 1. The authority citation for 21 CFR part 812 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b-263n.

■ 2. Section 812.119 is amended by revising paragraph (a) to read as follows:

**§ 812.119 Disqualification of a clinical investigator.**

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the

question of whether the investigator is entitled to receive investigational devices.

\* \* \* \* \*

Dated: December 12, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-21952 Filed 12-21-06; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9278]

RIN 1545-BB31, 1545-AY38, 1545-BC52

**Treatment of Services Under Section 482; Allocation of Income and Deductions From Intangibles; Stewardship Expense; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correcting amendments.

**SUMMARY:** This document contains corrections to final and temporary regulations (TD 9278) that was published in the **Federal Register** on Friday, August 4, 2006 (71 FR 44466) regarding the treatment of controlled services transactions under section 482 and the allocation of income from intangibles, in particular with respect to contributions by a controlled party to the value of an intangible owned by another controlled party. This document also contains corrections to final and temporary regulations that modify the regulations under section 861 concerning stewardship expenses to be consistent with the changes made to the regulations under section 482.

**DATES:** *Effective Date:* The amendments are effective on January 1, 2007.

**FOR FURTHER INFORMATION CONTACT:** Thomas A. Vidano, (202) 435-5265, or Carol B. Tan (202) 435-5159, for matters relating to section 482, and David F. Bergkuist, (202) 622-3850, for matters relating to stewardship expenses (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

The final and temporary regulations that are the subject of these corrections are under sections 482 and 861 of the Internal Revenue Code.

**Need for Correction**

As published, the final and temporary regulations (TD 9278) contains errors that may prove to be misleading and are in need of clarification.