Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA)(5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

Based on Committee data, there are nine producers (eight of whom are also handlers) in the regulated area and nine handlers (eight of whom are also producers) subject to regulation under the order. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those having annual receipts of less than $7,000,000.

Also based on Committee data, 825,617 hundredweight of Colorado Area No. 3 potatoes were produced for the fresh market during the 2007 season. Based on National Agricultural Statistics Service (NASS) data, the average producer price for Colorado summer potatoes for 2007 was $7.75 per hundredweight. The average annual producer revenue for the nine Colorado Area No. 3 potato producers is therefore calculated to be approximately $710,948. Using Committee data regarding each individual handler's total shipments during the 2007–2008 fiscal period and a Committee estimated average f.o.b. price for 2007 of $9.95 per hundredweight ($7.75 per hundredweight plus estimated packing and handling costs of $2.20 per hundredweight), all of the Colorado Area No. 3 potato handlers ship under $7,000,000 worth of potatoes. Thus, the majority of handlers and producers of Colorado Area No. 3 potatoes may be classified as small entities.

This rule continues in effect the action that provided for the handling of all varieties of potatoes with a minimum diameter of ¾ inch, if they otherwise meet the requirements of U.S. No. 1 grade. This change enables handlers to respond to consumer demand for small potatoes. Authority for regulating grade and size is provided in § 948.22 of the order. Section 948.387(a) of the order's administrative rules and regulations prescribes the actual size requirements.

This action is expected to have a beneficial impact on handlers and producers due to the increased volume of potatoes. There should be no extra cost to producers or handlers because current harvesting and handling methods can accommodate the sorting of these smaller potatoes. The size relaxation will result in a greater quantity of potatoes meeting the minimum requirements of the handling regulation. This should translate into an increased market for small potatoes and greater returns for handlers and producers.

By providing Colorado Area No. 3 handlers the flexibility to pack smaller potatoes, the Committee believes the industry will remain competitive in the marketplace. The small potato market is a premium market and this action is expected to further increase sales of Colorado potatoes to benefit the Colorado potato industry. The benefits of this rule are not expected to be disproportionately greater or lesser for small entities than for large entities.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large potato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Committee's meetings were widely publicized throughout the Colorado potato industry and all interested persons were invited to participate in Committee deliberations. Like all Committee meetings, the June 4 and November 17, 2009, meetings were public meetings and all entities, both large and small, were able to express views on this issue.

Comments on the interim rule were required to be received on or before June 4, 2010. No comments were received. Therefore, for reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: *http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480acfc3d.*

This action also affirms information contained in the interim rule concerning Executive Orders 12866 and 12988, the Paperwork Reduction Act (44 U.S.C. Chapter 35), and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (75 FR 17034, April 5, 2010) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 948

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

PART 948—IRISH POTATOES GROWN IN COLORADO—[AMENDED]

■ Accordingly, the interim rule that amended 7 CFR part 948 and that was published at 75 FR 17034 on April 5, 2010, is adopted as a final rule, without change.

Dated: June 29, 2010.

Robert C. Keeney,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 2010–16337 Filed 7–2–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2010–N–0002]

Implantation or Injectable Dosage Form New Animal Drugs; Propofol

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 new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The NADA provides for veterinary prescription use of propofol as an anesthetic in dogs and cats.

DATES: This rule is effective July 6, 2010.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, email: *melanie.berson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017 filed NADA 141–303 that provides for veterinary prescription use of PROPOCLEAR (propofol) in dogs and

cats for induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic. The application is approved as of May 21, 2010, and the regulations are amended in 21 CFR 522.2005 to reflect the approval.

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 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.

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 on the date of approval.

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 § 522.2005, revise paragraphs (b) and (c) to read as follows:

§ 522.2005 Propofol.

* * * * *

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 059130 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 000074 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(3) No. 000856 for use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection according to label directions. The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use*—(i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic.

* * * * *

Dated: June 29, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010–16301 Filed 7–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 53, 54, 301 and 602

[TD 9492]

RIN 1545–BG18

Excise Taxes on Prohibited Tax Shelter Transactions and Related Disclosure Requirements; Disclosure Requirements With Respect to Prohibited Tax Shelter Transactions; Requirement of Return and Time for Filing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations that provide guidance under section 4965 of the Internal Revenue Code (Code), relating to entity-level and manager-level excise taxes with respect to prohibited tax shelter transactions to which tax-exempt entities are parties; sections 6033(a)(2) and 6011(g), relating to certain disclosure obligations with respect to such transactions; and sections 6011 and 6071, relating to the requirement of a return and time for filing with respect to section 4965 taxes. This action is necessary to implement section 516 of the Tax Increase Prevention Reconciliation Act of 2005. These final regulations affect a broad array of tax-exempt entities, including charities, state and local government entities, Indian tribal governments and employee benefit plans, as well as entity managers of these entities.

DATES: *Effective Date:* These regulations are effective July 6, 2010.

Applicability Date: For dates of applicability, see §§ 1.6033–5(f), 53.4965–9(b) and (c), 53.6071–1(h), 54.6011–1(d), 301.6011(g)–1(j) and 301.6033–5(b).

FOR FURTHER INFORMATION CONTACT: For questions concerning these regulations, contact Benjamin Akins at (202) 622–1124 or Michael Blumenfeld at (202) 622–6070. For questions specifically relating to qualified pension plans, individual retirement accounts, and similar tax-favored savings arrangements, contact Cathy Pastor at (202) 622–6090 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545–2079. The collection of information in these final regulations is in § 301.6011(g)–1. The collection of information in § 301.6011(g)–1 flows from section 6011(g), which requires a taxable party to a prohibited tax shelter transaction to disclose to any tax-exempt entity that is a party to the transaction that the transaction is a prohibited tax shelter transaction. The likely recordkeepers are taxable entities or individuals that participate in prohibited tax shelter transactions. The estimated number of recordkeepers is between 1,250 and 6,500. The information that is required to be collected for purposes of § 301.6011(g)–1 is a subset of information that is required to be collected in order to complete and file Form 8886, "Reportable Transaction Disclosure Statement." The estimated paperwork burden for taxpayers filling out Form 8886 is approved under OMB number 1545–1800.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control