

# Rules and Regulations

Federal Register

Vol. 76, No. 153

Tuesday, August 9, 2011

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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 946

[Doc. No. AMS-FV-11-0024; FV11-946-3 FIR]

#### Irish Potatoes Grown in Washington; Modifications of the Rules and Regulations

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Affirmation of interim rule as final rule.

**SUMMARY:** The Department of Agriculture is adopting, as a final rule, without change, an interim rule that extended the one-year suspension of the minimum quality, maturity, pack, marking, and inspection requirements prescribed for russet potato varieties under the Washington potato marketing order for the 2011–2012 and subsequent fiscal periods. The interim rule also extended the reporting requirement for russet potato handlers for the purpose of obtaining information necessary for administering the marketing order. This change is expected to reduce overall industry expenses and increase net returns to producers and handlers while allowing the industry the opportunity to continue exploring alternative marketing strategies.

**DATES:** Effective August 10, 2011.

**FOR FURTHER INFORMATION CONTACT:** Teresa Hutchinson or Gary Olson, Northwest Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, Telephone: (503) 326-2724, Fax: (503) 326-7440, or E-mail: [Teresa.Hutchinson@ams.usda.gov](mailto:Teresa.Hutchinson@ams.usda.gov) or [GaryD.Olson@ams.usda.gov](mailto:GaryD.Olson@ams.usda.gov).

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web

site: <http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide>; or by contacting Laurel May, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: [Laurel.May@ams.usda.gov](mailto:Laurel.May@ams.usda.gov).

**SUPPLEMENTARY INFORMATION:** This rule is issued under Marketing Order No. 946, as amended (7 CFR part 946), regulating the handling of Irish potatoes grown in Washington, hereinafter referred to as the “order.” The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.”

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Order 12866.

The handling of potatoes grown in Washington is regulated by 7 CFR part 946. This rule continues in effect the interim rule that extended the one-year suspension of the order’s handling regulation for russet potato varieties for the 2011–2012 and subsequent fiscal periods. This change also extended the reporting requirement for russet potato handlers to obtain information necessary for the collection of assessments and statistical data. This change allows the Washington potato industry to continue marketing russet potatoes without regard to the minimum quality, maturity, pack, marking, and inspection requirements prescribed under the Washington potato marketing order.

In an interim rule published in the **Federal Register** on May 13, 2011, and effective on July 1, 2011, (76 FR 27850, Doc. No. AMS-FV-11-0024, FV11-946-3 IR), the introductory text of §§ 946.143 and 946.336 were amended by removing text referring to the temporary suspension and replacing it with text referring to a permanent suspension.

#### 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.

There are 43 handlers of Washington potatoes subject to regulation under the order (inclusive of the 33 russet potato handlers) and approximately 267 producers in the regulated production area. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.201) as those having annual receipts of less than \$7,000,000, and small agricultural producers are defined as those having annual receipts of less than \$750,000.

During the 2009–2010 fiscal period, the Committee reports that 9,765,131 hundredweight of Washington potatoes were shipped into the fresh market. Based on average f.o.b. prices estimated by the USDA’s Economic Research Service and Committee data on individual handler shipments, the Committee estimates that 42, or approximately 98 percent of the handlers, had annual receipts of less than \$7,000,000.

In addition, based on information provided by the National Agricultural Statistics Service, the average producer price for Washington potatoes for 2010 was \$7.55 per hundredweight. The average gross annual producer revenue for each of the 267 Washington potato producers is therefore calculated to be approximately \$276,130. In view of the foregoing, the majority of Washington potato producers and handlers may be classified as small entities.

This rule continues in effect the action that extended the one-year suspension of the handling regulation for russet potato varieties for the 2011–2012 and subsequent fiscal periods. This rule also continues in effect the action that extended the reporting requirement for russet potato handlers to obtain information necessary to administer the order. This change is expected to reduce overall industry expenses while providing the industry with the opportunity to continue exploring alternative marketing strategies. This rule amends the

introductory text in §§ 946.143 and 946.336. Authority for the change in the order's rules and regulations is provided for in §§ 946.70 and 946.52, respectively.

This action is not expected to increase costs associated with the order requirements. Rather, this action represents a cost savings for handlers and has the potential to increase industry returns. This change extends the one-year suspension of minimum quality, maturity, pack, marking, and inspection requirements indefinitely. Though inspections will not be mandated for russet potatoes handled under the order, handlers may at their discretion choose to have their potatoes inspected. Handlers are thus able to control costs—which are generally passed on to producers—based on the demands of their customers. The opportunities and benefits of this rule are equally available to all Washington potato handlers and growers, regardless of their size.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581-0178 (Vegetable and Specialty Crop Marketing Orders). No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This change continues the monthly reporting requirement for russet potato handlers. The reports provide the Committee with information necessary to track shipments and collect assessments. 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 meeting was widely publicized throughout the Washington potato industry and all interested persons were invited to participate in Committee deliberations. Like all Committee meetings, the January 26, 2011, meeting was a public meeting, 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 July 12, 2011. No comments were received. Therefore, for the 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/#!documentDetail;D=AMS-FV-11-0024-0001>.

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** (76 FR 27850, May 13, 2011) will tend to effectuate the declared policy of the Act.

**List of Subjects in 7 CFR Part 946**

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

Accordingly, the interim rule that amended 7 CFR 946.143 and 946.336 and that was published at 76 FR 27850 on May 13, 2011, is adopted as a final rule, without change.

Dated: August 3, 2011.  
**David R. Shipman**,  
*Acting Administrator, Agricultural Marketing Service.*  
[FR Doc. 2011-20124 Filed 8-8-11; 8:45 am]  
**BILLING CODE 3410-02-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 520, 522, and 524**

[Docket No. FDA-2011-N-0003]

**New Animal Drugs; Change of Sponsor; Moxidectin**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for three approved new animal drug applications (NADAs) for dosage form products containing moxidectin from Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., to Boehringer Ingelheim Vetmedica, Inc.

**DATES:** This rule is effective August 9, 2011.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary

Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, e-mail: [steven.vaughn@fda.hhs.gov](mailto:steven.vaughn@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 has informed FDA that it has transferred ownership of, and all rights and interest in, the following three approved NADAs for dosage form products containing moxidectin to Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002: NADA 141-099, NADA 141-220, and NADA 141-247. Accordingly, the Agency is amending the regulations in 21 CFR parts 520, 522, and 524 to reflect the transfer of ownership.

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 Parts 520, 522, and 524**

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 parts 520, 522, and 524 are amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.1454, revise paragraphs (b) and (d) to read as follows:

**§ 520.1454 Moxidectin solution.**

\* \* \* \* \*  
(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.  
\* \* \* \* \*

(d) *Special considerations.* See § 500.25 of this chapter.  
\* \* \* \* \*

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

■ 4. In § 522.1450, redesignate paragraph (d) as paragraph (e); add new paragraph (d); and revise paragraph (b)