

FR 73995, December 5, 2008), with a change, will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 984

Walnuts, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

■ Accordingly, the interim final rule amending 7 CFR part 984, which was published at 73 FR 73995 on December 5, 2008, is adopted as a final rule with the following change:

PART 984—WALNUTS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 984 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. In § 984.437 paragraphs (a) and (b) are revised to read as follows:

§ 984.437 Methods for proposing names of additional candidates to be included on walnut growers' nomination ballots.

(a) With regard to Board grower member positions specified in § 984.35(a)(5) and (b)(6), any ten or more such growers who marketed an aggregate of 500 or more tons of walnuts through handlers who did not handle 35% or more of the crop during the marketing year preceding the year in which Board nominations are held, may petition the Board to include on the nomination ballot the name of an eligible candidate for this position, and the name of an eligible candidate to serve as his or her alternate. The names of the eligible candidates proposed pursuant to this paragraph shall be included on the ballot together with the names of any incumbents who are willing to continue serving on the Board.

(b) Any ten or more growers eligible to serve in the grower member positions specified in § 984.35(a)(3) and (4) or § 984.35(b)(4) and (5) and who marketed an aggregate of 500 or more tons of walnuts through handlers who did not handle 35% or more of the crop during the marketing year preceding the year in which Board nominations are held, may petition the Board to include on the nomination ballot for a district the name of an eligible candidate for the applicable position, and the name of an eligible candidate to serve as his or her alternate. The names of the eligible candidates proposed pursuant to this paragraph shall be included on the ballot together with the names of any incumbents who are willing to continue serving on the Board.

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Dated: February 24, 2009.

Robert C. Keeney,

Acting Associate Administrator.

[FR Doc. E9–4291 Filed 2–27–09; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1220

[Doc. No. AMS–LS–08–0074]

Soybean Promotion, Research, and Information Program: Amend Procedures To Request a Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the procedures to request a referendum under the Soybean Promotion, Research, and Consumer Information program, commonly known as the soybean checkoff program, by updating the number of soybean producers in the United States. The number of soybean producers, based on information provided by the Department of Agriculture (USDA), Farm Service Agency (FSA), is 589,182.

Additionally, this rule amends the regulations pursuant to administrative changes to Web site addresses and office locations made for the USDA's Agricultural Marketing Service (AMS).

DATES: *Effective Date:* March 3, 2009.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Payne, Chief, Marketing Programs Branch, Livestock and Seed Program, AMS, USDA, Room 2628–S, STOP 0251, 1400 Independence Avenue, SW., Washington, DC 20250–0251; Telephone 202/720–1115; Fax 202/720–1125; or e-mail to Kenneth.Payne@usda.gov.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Office of Management and Budget (OMB) has waived the review process required by Executive Order 12866 for this action.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule is not intended to have a retroactive effect. The final rule would not preempt any other Federal or State laws, regulations, or policies.

The Soybean Promotion, Research, and Consumer Information Act (Act) provides that administrative

proceedings must be exhausted before parties may file suit in court. Under section 1971 of the Act, a person subject to the Soybean Promotion and Research Order (Order) may file a petition with USDA stating that the Order, any provision of the Order, or any obligation imposed in connection with the Order, is not in accordance with the law and requesting a modification of the Order or an exemption from the Order. The petitioner is afforded the opportunity for a hearing on the petition. After a hearing, USDA would rule on the petition. The Act provides that district courts of the United States in any district in which such person is an inhabitant, or has their principal place of business, has jurisdiction to review USDA's ruling on the petition, if a complaint for this purpose is filed within 20 days after the date of the entry of the ruling.

Further, section 1974 of the Act provides, with certain exceptions, that nothing in the Act may be construed to preempt or supersede any other program relating to soybean promotion, research, consumer information, or industry information organized under the laws of the United States or any State. One exception in the Act concerns assessments collected by Qualified State Soybean Boards (QSSBs). The exception provides that to ensure adequate funding of the operations of QSSBs under the Act, no State law or regulation may limit or have the effect of limiting the full amount of assessments that a QSSB in that State may collect, and which is authorized to be credited under the Act. Another exception concerns certain referenda conducted during specified periods by a State relating to the continuation of a QSSB or State soybean assessment.

Regulatory Flexibility Act

AMS has determined that this final rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612). The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened.

For the purpose of the Request for Referendum, the Secretary will use the most recent number of soybean producers identified by USDA's FSA. The latest number of soybean producers identified by FSA is 589,182 and was obtained using information from 2006 and 2007 acreage reports. The data were sorted in such a manner as to include all producers that were engaged in the production of soybeans in at least one

of the 2 years and exclude counting a producer more than once if that producer engaged in production during both years. Therefore, the number of soybean producers, as presented in the proposed rule, who would be eligible to participate in the Request for Referendum will be changed from 663,880 to 589,182. The majority of producers subject to the Order are small businesses under the criteria established by the Small Business Administration (SBA) [13 CFR 121.201]. SBA defines small agricultural producers as those having annual receipts of less than \$750,000.

Further, the information collection requirements are minimal. Requesting form LS-51-1 to participate in a Request for Referendum may be done by mail, in-person, by facsimile, or via the Internet and would not impose a significant economic burden on participants. Finally, this final rule will amend, as described in the proposed rule, the regulations pursuant to administrative changes to Web site addresses and office locations for the AMS.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the reporting and recordkeeping requirements included in 7 CFR part 1220 were previously approved by OMB and were assigned control number 0581-0093.

Background

The Act (7 U.S.C. 6301-6311) provides for the establishment of a coordinated program of promotion and research designed to strengthen the soybean industry's position in the marketplace, and to maintain and expand domestic and foreign markets and uses for soybeans and soybean products. The program is financed by an assessment of 0.5 of 1 percent of the net market price of soybeans sold by producers. The final rule establishing a Soybean Promotion, Research, and Consumer Information program was published in the July 9, 1991 issue of the **Federal Register** (56 FR 31043) and assessments began on September 1, 1991.

The Act required that an initial referendum be conducted no earlier than 18 months and not later than 36 months after the issuance of the Order to determine whether the Order should be continued. The initial referendum was conducted on February 9, 1994. On April 1, 1994, the Secretary announced that of the 85,606 valid ballots cast, 46,060 (53.8 percent) were in favor of continuing the Order and the remaining

39,546 votes (46.2 percent) were against continuing the Order. The Act required approval by a simple majority for the Order to continue.

The Act also required that within 18 months after the Secretary announced the results of the initial referendum, the Secretary would conduct a poll among producers to determine if producers favored a referendum on the continuance of the payment of refunds under the Order. On December 5, 2008, USDA published a proposed rule in the **Federal Register** (73 FR 74080) to amend the procedures for soybean producers to request a referendum on the Order.

A July 25, 1995, nationwide poll of soybean producers did not generate sufficient support for a refund referendum to be held. A refund referendum would have been held if at least 20 percent (not in excess of one-fifth of which may be producers in any one State) of the 381,000 producers (76,200) nationwide requested it. Only 48,782 soybean producers participated in the poll. Consequently, refunds were discontinued on October 1, 1995.

The Act also specifies that the Secretary shall, 5 years after the conduct of the initial referendum and every 5 years thereafter, provide soybean producers an opportunity to request a referendum on the Order. Additionally, the Act specifies that these subsequent polls require that at least 10 percent (not in excess of one-fifth in any one State) of all producers must request a referendum in order to trigger the conduct of a referendum. If a referendum is requested, it will be held within 1 year of that determination.

On October 1, 1999, through November 16, 1999, a nationwide Request for Referendum was conducted to determine if there was sufficient interest among soybean producers to vote on whether to continue the soybean checkoff program. Ten percent of the 600,813 soybean producers nationwide (not in excess of one-fifth of which may be producers in any one State) needed to participate in the Request for Referendum to trigger a referendum. Only 17,970 eligible soybean producers completed valid requests.

Five years later, another Request for Referendum was conducted May 1, 2004, through May 28, 2004. As in the prior Request for Referendum, the purpose was to determine if there was sufficient interest among soybean producers to vote on whether to continue the soybean checkoff Program. To be eligible to participate in the Request for Referendum, producers or the producer entity that they are authorized to represent had to certify

and provide supporting documentation showing that they or the producer entity they represent paid an assessment sometime during the representative period between January 1, 2002 and December 31, 2003. Of the total 663,880 soybean producers eligible to participate, 3,206 valid Requests for Referendum were completed. This number did not meet the requisite number of 66,388; therefore, a referendum was not conducted.

In accordance with the Act, another Request for Referendum will be conducted in 2009. In the proposed rule, data provided by USDA's FSA was presented that would amend the number of soybean producers in preparation for this upcoming Request for Referendum. Presently, section 1220.616 of the Order states that the number of soybean producers in the United States is 663,880. This final rule amends the number of eligible producers based on information from acreage reports provided by FSA which identifies 589,182 soybean producers for crop years 2006 and 2007. The data were sorted in such a manner as to include all producers that were engaged in the production of soybeans in at least one of the 2 years and exclude counting a producer more than once if that producer engaged in production during both years. Using the last two crop years for which complete data is available ensures that all eligible producers are counted, as some producers use soybeans in rotation with other crops and do not plant soybeans every year or the market for some producers in a particular crop year may not have been conducive to growing soybeans. This methodology is consistent with that used during the last amendment to section 1220.616 in 2004.

In addition to the changes presented in the proposed rule relating to the number of eligible soybean producers, AMS also proposed amendments to sections 1220.622 and 1220.628 to update Web site addresses and office locations as a result of internal changes within the agency.

Discussion of Comments

In the December 5, 2008, proposed rule in the **Federal Register** (73 FR 74080), interested persons were provided the opportunity to comment on the changes to section 1220.616 of the regulations. The comment period ended December 22, 2008.

USDA received one comment raising a number of issues concerning the 2009 Request for Referendum, including the timing of the poll. The comment, however, did not address the proposed changes to section 1220.616. The 2009

Request for Referendum will be conducted in accordance with the Act and applicable regulations. Pursuant to 5 U.S.C. 553, good cause is found for not postponing the effective date of the action until 30 days after publication in the **Federal Register** in order to conduct the Request for Referendum within the timeframes that appear in the Act.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Reporting and recordkeeping requirements, Soybeans and soybean products.

■ For the reasons set forth in the preamble, 7 CFR part 1220 is amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

■ 1. The authority citation for part 1220 continues to read as follows:

Authority: 7 U.S.C. 6301–6311 and 7 U.S.C. 7401.

Subpart F—Procedures to Request a Referendum

■ 2. In § 1220.616, paragraph (d) is revised to read as follows:

§ 1220.616 General.

* * * * *

(d) For purposes of paragraphs (b) and (c) of this section, the number of soybean producers in the United States is determined to be 589,182.

§ 1220.622 [Amended]

■ 3. In § 1220.622, paragraph (b) the Web site “<http://www.ams.usda.gov/lsg/mpb/rp-soy.htm>” is removed and a new Web site “<http://www.ams.usda.gov/lsmarketingprograms>” is added in its place.

■ 4. In § 1220.628, paragraph (a) is revised to read as follows:

§ 1220.628 Results of the request for referendum.

(a) The Administrator, FSA, shall submit to the Administrator, AMS, the reports from all State FSA offices. The Administrator, AMS shall tabulate the results of the Request for Referendum. USDA will issue an official press release announcing the results of the Request for Referendum and publish the same results in the **Federal Register**. In addition, USDA will post the official

results at the following Web site: “<http://www.ams.usda.gov/lsmarketingprograms>”.

Subsequently, State reports and related papers shall be available for public inspection upon request during normal business hours in the Marketing Programs Branch office, Livestock and Seed Program, AMS, USDA, Room 2628–S, STOP 0251, 1400 Independence Avenue, SW., Washington, DC.

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Dated: February 24, 2009.

Robert C. Keeney,

Acting Associate Administrator.

[FR Doc. E9–4292 Filed 2–27–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2009–N–0665]

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The supplemental ANADA adds claims for persistent effectiveness against various species of external and internal parasites when cattle are treated with a 1-percent ivermectin solution by subcutaneous injection.

DATES: This rule is effective March 2, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–228 that provides for use of PHOENECTIN (ivermectin) Injection 1% for the treatment and control of parasites in cattle. The supplemental ANADA adds

claims for persistent effectiveness against various species of external and internal parasites of cattle. The supplemental ANADA is approved as of January 23, 2009, and the regulations are amended in 21 CFR 522.1192 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(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.

§ 522.1192 [Amended]

■ 2. In § 522.1192, in paragraph (b)(2), remove “No. 055529” and in its place add “Nos. 055529 and 059130”; and remove paragraph (b)(3).

Dated: February 18, 2009.

Steven D. Vaughn,

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

[FR Doc. E9–4304 Filed 2–27–09; 8:45 am]

BILLING CODE 4160–01–S