

Rules and Regulations

Federal Register

Vol. 85, No. 145

Tuesday, July 28, 2020

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1200

[Doc. No. AMS–SC–19–0105]

Administrative Procedures Governing Formulation of a Research and Promotion Order

AGENCY: Agricultural Marketing Service, Agriculture (USDA).

ACTION: Final rule.

SUMMARY: This rule establishes procedures to govern the formulation of new research and promotion programs—or orders—under the Commodity Promotion, Research, and Information Act of 1996 (Act). Research and promotion programs are administered by boards or councils with oversight by the United States Department of Agriculture (USDA). This rule specifies the process for proposing such programs to USDA. It also clarifies that USDA's Agricultural Marketing Service (AMS) will continue to require associations of producers or individuals proposing new programs to post a bond or other collateral to reimburse USDA for the costs of program development.

DATES: *Effective date:* August 27, 2020.

FOR FURTHER INFORMATION CONTACT: Heather Pichelman, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915; facsimile: (202) 205–2800; or electronic mail: Heather.Pichelman@usda.gov.

SUPPLEMENTARY INFORMATION: As authorized under the Act, this final rule adds a new subpart D to 7 CFR part 1200—Rules of Practice and Procedure Governing Proceedings Under Research, Promotion, and Information Programs. Subpart D addresses procedures specific to the formulation of new programs under the Act.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

Executive Order 13175

This action has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct effects on Tribal governments and would not have significant Tribal implications.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. 7 U.S.C. 7423 provides that the Act shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Background

This final rule establishes procedures to govern the formulation of new research and promotion programs under the Act. This rule also clarifies that AMS will continue to require associations of producers or individuals proposing new programs to post a bond or other collateral to reimburse USDA for the costs of program development.

Title 7 U.S.C. 7413(b)(1)(B) authorizes associations of producers of an agricultural commodity or other individuals to petition USDA to establish a research, promotion, and/or information program with respect to that commodity. The purpose of such programs is to provide a framework for agricultural industries to pool their resources and combine efforts to develop new markets, strengthen existing markets, and conduct important research and promotion activities. *See* 7 U.S.C. 7411(b).

USDA's Agricultural Marketing Service (AMS) oversees these programs. With this final rule, AMS is establishing the following procedures for formulating new programs so interested parties are aware of the process and requirements.

Under § 1200.202(a), an industry association or individuals may file a written proposal for a new research and promotion program with the AMS Administrator (Administrator). Under § 1200.202(b), the Administrator will consider whether there is broad industry support for the proposed program and whether proposed provisions of the program are authorized under the Act. The Administrator will also evaluate anticipated benefits to the industry and the economic feasibility of the program. Finally, the Administrator will consider whether the proposed program would tend to effectuate the declared policy of the Act. Under § 1200.202(c), if the Administrator determined that the program will not effectuate the policy of the Act, AMS will deny the proposal and would notify the proponent(s), explaining the grounds for denial. Under § 1200.202(d), if the Administrator determined that the proposed program will likely effectuate the purposes of the Act by benefitting producers, handlers, and importers of the commodity, or others in the marketing chain, the Administrator will notify the proponent(s) that AMS will proceed with program development and, in accordance with § 1200.204, the proponent(s) will be required to post a bond or other collateral to cover AMS expenses to develop the program.

The Act provides that once a board is established under an order, the Secretary of Agriculture (Secretary) must be reimbursed for all expenses incurred in the implementation,

administration, and supervision of the order, including all referendum costs incurred in connection with the order. The board uses assessment funds collected from regulated entities to reimburse the Secretary for program oversight.

However, AMS incurs substantial expenses in the development process leading to program establishment. AMS may conduct industry outreach meetings, solicit public input, analyze economic data, draft rulemaking documents, and conduct initial referenda. These activities are necessary to progress toward program establishment. Typical expenses for these preliminary activities may include, but not be limited to, employee time and travel, supplies, printing, and mailing.

In some cases, the proponent industry may elect to defer an initial referendum for up to three years after the program is established. In other cases, despite all efforts of the proponent and AMS to develop a new program, ultimately the proposed program may not be established. Nevertheless, under either of these scenarios, AMS will have already incurred expenses related to program development.

Section 7417(a)(2) of the Act provides that the Secretary can require the industry seeking a new program to post a bond or other collateral to cover the cost of the initial referendum. In § 1200.201, this rule defines *cost of the referendum* to mean all the expenses AMS incurs in the development of a potential new program, including the cost of conducting an initial referendum.

The amount of the bond or collateral required under § 1200.204 will be based on unique factors like the projected number of staff hours involved, the amount of staff travel necessary for outreach, the size and complexity of the proposed program, and the number of industry members to be polled in an initial referendum. This will ensure that AMS will be reimbursed on a timely basis for all expenses related to program development, even if the initial referendum is deferred or if the program is not established.

Section 1200.202(e) of this rule specifies that once AMS has worked with industries or individuals to develop a proposed order, AMS will publish the proposal in the **Federal Register** to allow public comments on the proposed program. Based on comments, AMS will determine whether to proceed with program establishment.

Under § 1200.203 of this rule, if AMS determined to proceed with program

establishment, the Administrator could conduct an initial referendum among the producers, handlers, and importers who would be subject to assessment under the program in order to determine whether they favor establishment of the program. The Act provides that USDA could also establish the program and defer the initial referendum for up to three years after the program is established. *See* 7 U.S.C. 7417(b). In either case, referendum voters will be those entities who, during a representative period determined by the Administrator, produced, handled, and/or imported the agricultural commodity. For referendum expenses incurred after a program is established, the Secretary will be reimbursed by the board appointed to administer the program, as provided by the Act. *See* 7 U.S.C. 7417(f).

Under § 1200.205 of this rule, if at any time during the development process, based on public comments, referendum votes, or other information available, AMS determines that the proposed program will not tend to effectuate the policy of the Act, the Administrator will terminate proceedings and will collect reimbursement for program development expenses from the bond or collateral posted by the program proponent(s).

This rule will also make other administrative provisions related to the establishment of a new program. Section 1200.201 will define other terms necessary for administration of the regulation. Section 1200.206 will provide for the issuance, effectuation, and publication of the new order.

Final Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities. 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. The purpose of research and promotion programs is to benefit all sizes of producers, handlers, and importers of an agricultural commodity.

The Act makes it possible for producer associations or other individuals engaged in specific agricultural commodity industries to submit a proposal for a new program. It is impossible for AMS to determine which industries may seek research and promotion programs in the future or to determine the number or size of business entities that might propose such programs. The expenses necessary for each program's development depend

on factors such as projected staff hours to develop the program, travel expenses related to outreach, size and complexity of the proposed program, and the size of the industry to be polled in a referendum. Based on its experience with past program proposals, AMS estimates that expenses for typical program development range from \$80,000 to \$150,000. Thus, under this rule, proponents could be required to post bonds or other collateral to cover those amounts if AMS agrees to proceed with program development. Costs to individuals or businesses will depend on the number of entities in each proponent group. Given that we don't know the identity or business size of future program proponents, AMS cannot determine what economic impact this rule might have on small entities. Based on experience with proponents seeking to establish new programs under the Act, AMS believes that this rule is unlikely to have a significant economic impact on a substantial number of small entities.

There will be no new direct costs associated with the implementation of this rule. This rule codifies procedures for proposing new research and promotion programs that have been practiced since the Act's adoption in 1996. In addition to specifying the program proposal process, the rule clarifies that the cost of the referendum to be covered by the required bond or collateral would include all the costs associated with program development.

Paperwork Reduction Act

No information collection or recordkeeping requirements are imposed on the public by this rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

As with all Federal research and promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

E-Government Act

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

A proposed rule concerning this action was published in the **Federal Register** on April 27, 2020 (85 FR 23246). A 30-day comment period ending on May 27, 2020, was provided to allow interested persons to respond to the proposal. The proposal was also

made available through the internet by USDA and the Office of the Federal Register.

Analysis of Comments

Two comments were received in response to the proposed rule. Of those comments, only one was substantive and related to this proposed rule. This commenter expressed a concern about the proposal. The commenter called the proposed rule a ridiculous idea.

AMS initiated this rule because it incurs substantial expenses in the development process leading to program establishment. The Act already requires the Secretary to be reimbursed for all expenses incurred in the implementation, administration, and supervision of the order, including all referenda costs incurred in connection with the order after a board has been established. This rule added expenses AMS incurs to develop a program to this requirement.

AMS has been requiring associations of producers or individuals proposing new programs to post a bond or other collateral to reimburse USDA for the costs of program development. This rule codifies this procedure, along with others, for proposing new research and promotion programs. These procedures have been practiced since the Act's adoption in 1996. Therefore, no changes have been made to this rule based on the comment.

A definition of "Secretary" has been added to the Definitions section to provide clarity.

After consideration of all relevant matters presented, including the information and recommendation submitted by the Board, the comments received, and other relevant information, it is hereby found that this rule, as hereinafter set forth, is consistent with and would effectuate the purposes of the Act.

List of Subjects in 7 CFR Part 1200

Administrative practice and procedure, Agricultural research, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS amends 7 CFR part 1200 as follows:

PART 1200—RULES OF PRACTICE AND PROCEDURE GOVERNING PROCEEDINGS UNDER RESEARCH, PROMOTION, AND INFORMATION PROGRAMS

■ 1. The authority citation for part 1200 continues to read as follows:

Authority: 7 U.S.C. 2101–2119, 2611–2627, 2701–2718, 2901–2911, 4501–4514, 4801–

4819, 4901–4916, 6101–6112, 6301–6311, 6401–6417, 7411–7425, 7481–7491, and 7801–7813.

■ 2. Add subpart D, consisting of §§ 1200.200 through 1200.206, to read as follows:

Subpart D—Administrative Procedures Governing Formulation of a Research and Promotion Order

Sec.	
1200.200	General.
1200.201	Definitions.
1200.202	Proposals.
1200.203	Initial referendum.
1200.204	Reimbursement of Secretary's expenses.
1200.205	Termination of proceedings.
1200.206	Execution of the order.

Authority: 7 U.S.C. 7411–7425.

§ 1200.200 General.

The terms defined/specified in this subpart shall apply to all research and promotion programs authorized under the Act.

§ 1200.201 Definitions.

Act means the Commodity Research, Promotion, and Information Act of 1996 (7 U.S.C. 7411–7425).

Administrator means the Administrator of the Agricultural Marketing Service or any officer or employee of the United States Department of Agriculture to whom authority has been delegated or may hereafter be delegated to act for the Administrator.

Cost of the Referendum means all USDA expenditures related to development of an order proposal, including, but not limited to, salaries, travel, supplies, printing, mailing, and shipping, and any costs related to an initial referendum.

Order means any order which may be issued pursuant to the Act.

Secretary means the United States Secretary of Agriculture or any officer or employee of the United States Department of Agriculture to whom authority has been delegated or may hereafter be delegated to act for the Secretary.

§ 1200.202 Proposals.

(a) An order may be proposed by any association of producers of an agricultural commodity, by any person that may be affected by the issuance of an order with respect to an agricultural commodity, or by the Secretary. Any person or organization other than the Secretary proposing an order shall file with the Administrator a written proposal.

(b) Upon receipt of a proposal, the Administrator shall investigate and evaluate the proposal.

(c) If the proposal is submitted by an association of producers of the agricultural commodity or by any person that may be affected by the issuance of an order, and the investigation and consideration lead the Administrator to conclude that the proposed order will not tend to effectuate the declared policy of the Act, the Administrator shall deny the proposal. The Administrator will promptly notify the proponent(s) of such denial, which will be accompanied by a brief statement of the grounds for the denial.

(d) If the proposal was submitted by an association of producers of the agricultural commodity or by any person that may be affected by the issuance of an order and the investigation and consideration lead the Administrator to conclude that an order will tend to effectuate the declared policy of the Act, the Administrator will promptly notify the proponent(s) of such conclusion, and the proponent(s) will be required to post a bond or other collateral in accordance with § 1200.204.

(e) If the Administrator concludes that an order will tend to effectuate the declared policy of the Act, the Administrator shall publish the proposed order in the **Federal Register** and give due notice and opportunity for public comment on the proposed order.

§ 1200.203 Initial referendum.

For the purpose of ascertaining whether the persons to be covered by an order favor the order going into effect, the Administrator may conduct an initial referendum among persons to be subject to an assessment under the order who, during a representative period determined by the Administrator, engaged in the production or handling of the agricultural commodity or the importation of the agricultural commodity.

§ 1200.204 Reimbursement of Secretary's expenses.

The Administrator may require any person or organization proposing an order to post a bond or other collateral to cover the cost of the referendum as defined in § 1200.201.

§ 1200.205 Termination of proceedings.

If at any time during development of a new program the Administrator concludes, based on public comments, referendum votes, or other available information, that an order will not tend to effectuate the declared policy of the Act, the Administrator shall terminate the proceedings and collect reimbursements from the bond or other

collateral posted pursuant to § 1200.204 for any expenses incurred in development of the proposed program.

§ 1200.206 Execution of the order.

(a) *Issuance of the order.* The Administrator shall, if the Administrator finds that it will tend to effectuate the purposes of the Act, issue the final order.

(b) *Effective date of order.* No order shall become effective in less than 30 days after its publication in the **Federal Register**, unless the Administrator, upon good cause found and published with the order, fixes an earlier effective date.

(c) *Notice of issuance.* After the Administrator issues the order, AMS will publish notice of the order's issuance in the **Federal Register**.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–15412 Filed 7–27–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2020–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2020. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective July 28, 2020.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary

Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2020, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (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, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: <https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room>. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: <https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 28, 2020 ...	141–466	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Narasin and nicarbazin and avilamycin Type C medicated broiler feeds.	Chickens	Supplemental approval of an increased age restriction and reduced withdrawal period in the use of MAXIBAN (narasin and nicarbazin) Type A medicated article) with INTEPRITY (avilamycin) Type A medicated articles in the manufacture of Type C medicated broiler feeds.	FOI Summary.
February 7, 2020 ...	200–614	Akorn Animal Health, Inc., 1925 West Field Ct., Suite 300, Lake Forest, IL 60045.	Pentobarbital Sodium and Phenytion Sodium Injectable Solution.	Dogs	Original approval as a generic copy of NADA 119–807.	FOI Summary.
February 27, 2020	141–521	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPARICA TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) Chewable Tablet.	Dogs	Original approval for the prevention of heartworm disease; kills adult fleas and is indicated for the treatment and prevention of flea infestations, the treatment and control of tick infestations, and the treatment and control of roundworm and adult hookworm infections for one month.	FOI Summary.
March 10, 2020	200–670	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, H62 FH90, Ireland.	SENERGY (selamectin) Topical Solution.	Dogs and cats	Original approval as a generic copy of NADA 141–152.	FOI Summary.