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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.

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 400

RIN 0563-AB84

General Administrative Regulations; Submission of Policies, Provisions of Policies, and Rates of Premium

AGENCY: Federal Crop Insurance Corporation.

ACTION: Interim rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the procedures for the submission of policies, plans of insurance, or other rates or premium by insurance companies, or other persons or entities, to the FCIC Board of Directors (Board) for approval for reinsurance and subsidy under section 508(h) of the Federal Crop Insurance Act (Act), in accordance with section 2108 of the 2001 Supplemental Appropriations Act.

This rule prescribes the respective roles and responsibilities of FCIC and the applicant. This rule also prescribes guidelines for the timing, content, and approval process for policies, plans of insurance, and rates of premium submitted under section 508(h) of the Act. In addition, this rule establishes requirements and guidelines for the reimbursement of research and development costs and maintenance costs for such submissions approved by the Board, and the payment of fees by insurance companies after the maintenance period has expired. This rule also provides guidelines for non-reinsured supplemental policies to be submitted to FCIC for review in accordance with the Standard Reinsurance Agreement (SRA).

EFFECTIVE DATES: This rule is effective September 17, 2001. Written comments and opinions on this interim rule will be accepted until close of business

November 16, 2001 and will be considered when the rule is to be made final. Comments to the General Administrative Regulations; Submission of Policies, Provisions of Policies, and Rates of Premium proposed rule published in the **Federal Register** on July 16, 2001, will be considered at the same time that comments are considered for this rule and those comments will not have to be resubmitted for consideration. The comment period for information collections under the Paperwork Reduction Act of 1995 continues through November 16, 2001.

ADDRESSES: Interested persons are invited to submit written comments to the Director, Product Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133. Comments titled "General Administrative Regulation; Submission of Policies, Provisions of Policies, and Rates of Premium" may be sent via the Internet to: DirectorPDD@rm.fcic.usda.gov. A copy of each response will be available for public inspection and copying from 7:00 a.m. to 4:30 p.m., CST, Monday through Friday, except holidays, at the above address.

FOR FURTHER INFORMATION CONTACT: Timothy Hoffmann, Director, Product Development Division, Federal Crop Insurance Corporation, at the Kansas City, MO, address listed above, telephone (816) 926-3707.

SUPPLEMENTARY INFORMATION

Executive Order 12866

The Office of Management and Budget (OMB) has determined that this rule is significant for the purpose of Executive Order 12866 and, therefore, it has been reviewed by OMB.

Paperwork Reduction Act of 1995

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501), the information collection and record keeping requirements included in this rule have been submitted for approval to OMB. Please submit written comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503. A comment to OMB is best assured of

having its full effect if OMB receives it within 30 days of publication of this rule.

Comments are being solicited from the public concerning this proposed information collection and record keeping requirements. This outside input will help:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumption used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission responses.)

Title: General Administrative Regulation; Submission of Policies, Provisions of Policies, and Rates of Premium.

Abstract: This rule revises guidelines for the submission of policies or other material to the Board under section 508(h) of the Act. In accordance with that section of the Act, this rule establishes the process for the submission of policies, plans of insurance, and rates of premium, the deadlines for the review and approval process by the Board, and the respective roles and responsibilities of FCIC and the applicant related to the submission. This rule specifies information that must be included in a new or revised submission and the format it must be in to be considered for Board approval. This rule establishes requirements and guidelines for the reimbursement of research and development costs and maintenance costs for such submissions approved by the Board and the payment of fees by insurance companies after the maintenance period has expired. It also requires non-reinsured supplemental policies developed by companies reinsured by FCIC to be submitted to FCIC for review in accordance with provisions contained in the Standard Reinsurance Agreement (SRA).

Purpose: To amend 7 CFR part 400 by revising subpart V.

Burden statement: This rule is needed to ensure that the Board receives complete submissions that are ready for review and approval. It also ensures the fair and equitable distribution of limited funds for research and development costs and maintenance costs. This rule will ensure an effective, orderly, and efficient crop insurance marketplace, and that the Federal crop insurance program is delivered to all producers in a manner that does not unfairly discriminate among producers or insurance companies.

The burden associated with this rule, with the exception of reading the rule, is in the development and submission of a policy, revision to a policy or rates of premium for any policy or plan authorized under the Act. FCIC estimates that annually 75 people (excluding Federal employees) will spend 2 hours reading this document for a total of 150 hours ($75 \times 2 = 150$). FCIC estimates people in 14 positions (marketing manager, computer manager, financial manager, technical writer, actuary, accountant, lawyer, economist, computer programmer, underwriter, paralegal, marketing researcher, statistician, and office assistant) will respond for a total of 210 respondents ($14 \text{ positions} \times 15 \text{ submissions} = 210$). FCIC estimates 105 annual responses ($15 \times 7 = 105$) due to 15 applicants completing seven objectives (preparing the submission, modifying the submission, corresponding with the Board, preparation and presentation to the Board, responding to issues, negotiating agreements, costs and fees and maintenance of approved products). To determine approximate annual burden hours, FCIC estimates 15 entities will prepare a submission (applicants) and will spend the following amount of time for each of the seven objectives: (1) Preparing and submitting the submission—22,500 hours ($15 \text{ applicants} \times 1,500 \text{ hours} = 22,500$); (2) Modifying the submission prior to Board approval—15,000 hours ($15 \text{ applicants} \times 1,000 \text{ hours} = 15,000$); (3) Preparation of correspondence between the Board and applicant—150 hours ($15 \text{ applicants} \times 10 \text{ hours} = 150$); (4) Preparation and presentation of the submission to the Board—600 hours ($15 \text{ applicants} \times 40 \text{ hours} = 600$); (5) Responding to procedural, policy, and data automation issues subsequent to Board approval—15,000 hours ($15 \text{ applicants} \times 1,000 \text{ hours} = 15,000$); (6) Negotiation of agreements, costs and fees—600 hours ($15 \text{ applicants} \times 40 \text{ hours}$); and (7) Maintenance of

approved products—3,000 hours ($15 \text{ applicants} \times 200 \text{ hours} = 3,000$).

Estimate of Burden: The public reporting burden for this collection of information is estimated to average 543 hours per response.

Respondents: Insurance companies, insureds, insurance agents, and other persons or entities who may wish to submit policies or policy provisions to the Board for approval.

Estimated Annual Number of Respondents: 210.

Estimated Annual Number of Responses Per Respondent: 0.5.

Estimated Annual Number of Responses: 105.

Estimated Total Annual Burden of Respondents: The total public burden for this rule is estimated at 57,000 hours.

Record keeping requirements: FCIC requires records to be kept for three years, and all records required by FCIC are retained as part of the normal business practice. Therefore, FCIC is not estimating additional burden related to record keeping.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 13132

The policies contained in this rule do not have a substantial direct effect on states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Nor does this rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

Regulatory Flexibility Act

This regulation will not have a significant economic impact on a substantial number of small entities. Additionally, the regulation does not require any greater action on the small entities than is required on the part of large entities. The amount of work required of the insurance companies will not increase because the information must already be collected

under the present policy. No additional work is required as a result of this action on the part of either the insured or the insurance companies. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605) and no Regulatory Flexibility Analysis was prepared.

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. The administrative appeal provisions published at 7 CFR part 11 or 7 CFR 400.169, as applicable, must be exhausted before any action for judicial review of any determination or action by FCIC may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

On July 16, 2001, FCIC published this rule as a proposed rule (66 FR 36951–36960). During the comment period, Congress enacted section 2103 of the 2001 Supplemental Appropriations Act, which authorized FCIC to promulgate this rule without regard to the notice and comment provisions of section 533 of title 5, United States Code, the Statement of Policy of the Secretary of Agriculture effective July 24, 1971, relating to notices of proposed rulemaking and public participation in rulemaking, and chapter 35 of title 44, United States Code. Congress also required that this rule be effective on the date of publication.

FCIC makes available standard policies for producers to insure certain

crops against various agricultural production risks and perils. Under the provisions of section 508(h) of the Act, (7 U.S.C. 1501 *et seq.*) any person may submit or propose other crop insurance policies, plans of insurance, provisions of policies, or rates of premium. These policies may be submitted without regard to limitations contained in the Act.

The Act requires that FCIC issue regulations to establish guidelines for the submission and Board review of policies or other material submitted to the Board under the Act. This rule prescribes guidelines for the timing, content, approval process, and the reimbursement for research and development costs and maintenance costs, and potential user fees for such submissions. This rule also clarifies the roles and responsibilities of FCIC and the applicant with respect to the submission. This rule also provides guidelines for non-reinsured supplemental policies to be submitted to FCIC for review in accordance with the SRA.

For submissions approved by the Board prior to publication of this regulation, applicants may either submit documentation of research and development costs or use a formula method to determine the amount of the research and development and maintenance reimbursement. The formula presented in this regulation is an objective measurement using the average number of policies per year earning premium from inception of the product to the time this regulation is published times \$7 with the result of this calculation adjusted for scope and complexity, as required by legislation. The \$7 was determined by using estimated product development costs with the intent to provide research and development cost reimbursement on an equitable basis considering the sales life cycle to date and market penetration.

Other technical corrections have been made as a result additional review and discussion with the Board.

List of Subjects in 7 CFR Part 400

Administrative practice and procedures, Crop insurance.

Interim Rule

Accordingly, for the reasons set forth in the preamble, the Federal Crop Insurance Corporation amends 7 CFR part 400 by revising Subpart V to read as follows:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS

Subpart V—Submission of Policies, Provisions of Policies and Rates of Premium

- Sec.
- 400.700 Basis, purpose, and applicability.
 - 400.701 Definitions.
 - 400.702 Confidentiality of submission and duration of confidentiality.
 - 400.703 Timing of submission.
 - 400.704 Type of submission.
 - 400.705 Contents required for a new submission or changes to a previously approved submission.
 - 400.706 Review of submission.
 - 400.707 Presentation to the Board for approval or disapproval.
 - 400.708 Approved submission.
 - 400.709 Roles and responsibilities.
 - 400.710 Preemption and premium taxation.
 - 400.711 Right of review, modification, and the withdrawal of reinsurance.
 - 400.712 Research and development reimbursement, maintenance reimbursement, and user fees.
 - 400.713 Non-reinsured supplemental (NRS) policy.

Authority: 7 U.S.C. 1506(1), 1506(p).

Subpart V—Submission of Policies, Provisions of Policies and Rates of Premium

§ 400.700 Basis, purpose, and applicability.

This subpart establishes guidelines for the submission of policies, plans of insurance, and rates of premium to the Board under section 508(h) of the Act and for non-reinsured supplemental policies in accordance with the SRA, and the roles and responsibilities of FCIC and the applicant. It also specifies the procedures for requesting reimbursement for research and development and maintenance costs for products and the approval process.

§ 400.701 Definitions.

Act. The Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*)

Actuarial documents. The forms and associated materials applicable to a crop or insurance year, which are available for public inspection in an agent's office and FCIC's website at www.act.fcic.usda.gov. These materials show the insurable acreage or commodities, the applicable guarantees, coverage levels, premium rates, insurable cropping practices common to the area, and other related information regarding crop insurance or other risk management plans of insurance in the county or state.

Actuarially appropriate. Premium rates determined to cover the anticipated loss and a reasonable reserve based on valid reasoning, an

examination of all known risk data, and founded on thorough knowledge or experience of the expected value of all future costs associated with a risk transfer.

Administrative and operating (A&O) subsidy. An amount for expenses associated with selling and servicing insurance products authorized by the Act and paid by FCIC on behalf of the producer to approved insurance providers.

Applicant. Any person or entity that submits a policy, provisions of a policy, or premium rates to the Board for approval under section 508(h) of the Act.

Approved insurance provider. A private insurance company that has been approved by FCIC to provide insurance coverage to producers participating in programs authorized by the Act.

Board. The Board of Directors of FCIC.

Complexity. Complexity takes into consideration such factors as originality, the number and type of factual determinations necessary to establish insurable interest, evaluate risk, and determine whether an indemnity is payable, the number of commodities and areas to which the product is applicable, the rating methodology, the number of risks covered, unique policy provisions or endorsements, the delivery process of the submission, and the process of creating rules, policy terms and conditions, underwriting procedures, rating methodologies, administrative and operating procedures, and supporting materials.

Development. The process of creating rules, methodologies, administrative and operating procedures, supporting materials, and documentation necessary to submit, gain approval, and implement a proposed policy or coverage.

Endorsement. A document appended to a policy reinsured under the Act that supplements or amends the insurance coverage of that policy.

FCIC. The Federal Crop Insurance Corporation, a wholly owned government corporation within USDA.

Maintenance. The process of continual support and improvement, as needed, for a policy or plan of insurance, including the periodic review of setting prices, updating premium rates or the rating methodology, updating or modifying policy terms and conditions, expanding into new commodities and areas, and other measures necessary to assure financial viability and actuarial soundness or to respond to statutory or regulatory changes.

Maintenance costs. Specific expenses associated with the maintenance of a policy during the maintenance period.

Maintenance period. A period of time that begins on the date the Board approves the submission for maintenance and ends on the date that is not more than four reinsurance years after such approval.

Manager. The Manager of FCIC.

Marketable. An evaluation by the Board of the marketing plan submitted by the applicant that determines that producers will purchase the product and approved insurance providers will sell the product based on credible evidence provided by the applicant.

Marketing plan. A detailed, written plan that identifies, at a minimum, the expected number of potential buyers, premium, and liability, the data upon which such information is based and a prescribed insurance year cycle.

Multiple peril crop insurance (MPCI). All insurance policies reinsured by FCIC that offers coverage for loss of production.

National Agricultural Statistics Service (NASS). An agency of the United States Department of Agriculture, or a successor agency.

Non-reinsured supplemental policy (NRS). A policy, endorsement or other risk management tool that is developed by an approved insurance provider, or an entity affiliated in some manner with an approved insurance provider, that offers coverage, other than for loss related to hail, for commodities in addition to coverage available under a policy or plan of insurance that is reinsured by FCIC. This policy, endorsement or other risk management tool has not been submitted under 508(h) for FCIC approval for reinsurance.

Non-significant changes. Minor changes to the policy or plan of insurance, such as technical corrections, that do not affect the rating or pricing methodologies, the amount of subsidy owed, the amount of coverage, the interests of producers, FCIC's reinsurance risk, or any condition that may affect liability or the amount of loss to be paid under the policy. This includes any changes due to statutory or regulatory requirements.

Policy. A contract for insurance that includes an application, Basic Provisions, applicable commodity provisions, other applicable options and endorsements, the actuarial documents for the insured commodity, and related materials.

Plan of insurance. A class of policies, such as MPCI or Crop Revenue Coverage, that offer a specific type of

coverage to one or more agricultural commodities.

Rate of premium. The dollar amount per insured unit or percentage rate per dollar of liability that is needed to pay anticipated losses and provide a reasonable reserve.

Related materials. The actuarial documents, special provisions, and any underwriting or loss adjustment manuals, handbooks, forms or other materials.

Research. The processes used to determine the need, producer interest, if the product is marketable, and feasibility of a proposed policy, plan of insurance or rate of premium.

Research and development costs. Specific expenses incurred and directly related to research and development of a submission approved by the Board.

Revenue insurance. Plans of insurance providing protection against loss of income or change in price.

Risk Management Agency (RMA). An agency of USDA responsible for the administration of all programs authorized under the Act and other authorities.

Risk subsidy. The portion of the approved premium paid by FCIC on behalf of the insured person.

Sales closing date. The final calendar date on which an approved insurance provider may accept an application by a producer for insurance.

Secretary. The Secretary of the United States Department of Agriculture.

Significant change. Any change to the policy or plan of insurance that may affect the rating and pricing methodologies, the amount of subsidy owed, the amount of coverage, the interests of producers, FCIC's reinsurance risk, or any condition that may affect liability or the amount of loss to be paid under the policy.

Special Provisions. The part of the policy that contains specific provisions of insurance for each insured crop that may vary by geographic area.

Submission. A policy, plan of insurance, provision of a policy or plan of insurance, or rates of premium provided by an applicant to FCIC in accordance with the requirements of this subpart.

USDA. The United States Department of Agriculture.

User fees. Fees, approved by the Board, that can be charged to approved insurance providers for use of a policy or plan of insurance.

§ 400.702 Confidentiality of submission and duration of confidentiality.

(a) Prior to approval by the Board, any submission made to the Board under section 508(h) of the Act, including any

information generated from the submission, will be considered confidential commercial or financial information for purposes of 5 U.S.C. 552(b)(4) and will not be released by FCIC to the public, unless the applicant authorizes such release in writing.

(b) Once the Board approves a submission, all information provided with the submission, or generated in the approval process, may be released to the public, including any mathematical modeling and data, unless it remains confidential business information under 5 U.S.C. 552(b).

(c) Any submission disapproved by the Board will remain confidential commercial or financial information in accordance with 5 U.S.C. 552(b) and no information related to such submission will be released by FCIC unless authorized in writing by the applicant.

§ 400.703 Timing of submission.

(a) A submission may only be provided to FCIC the first 5 business days of the months of, January, April, July, and October.

(b) Any submission not provided within the first 5 business days of a month stated in paragraph (a) of this section, will be considered to have been provided the next month stated in paragraph (a). For example, if an applicant provides a submission on the January 10, it will be considered to have been received on April 1.

(c) Any submission must be provided to the Deputy Administrator, Research and Development (or any successor), Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133-4676, not later than 180 days prior to the earliest proposed sales closing date to be considered for sale in the requested crop year.

§ 400.704 Type of submission.

(a) An applicant may submit to the Board in accordance with § 400.705:

(1) A policy or plan of insurance not currently reinsured by FCIC;

(2) One or more proposed revisions to a policy or plan of insurance authorized under the Act; or

(3) Rates of premium for any policy or plan of insurance authorized under the Act.

(b) An applicant must submit to the Board any significant change to a previously approved submission prior to making the change.

§ 400.705 Contents required for a new submission or changes to a previously approved submission.

A complete submission must contain the following material, as applicable, in the order given, in a 3-ring binder, with

section dividers clearly labeling each section. The entire submission must be included in an electronic format acceptable to RMA. Six identical copies of each submission must be sent to the Deputy Administrator, Research and Development (or successor), Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133-4676, and one identical copy of each submission provided to the Administrator, Risk Management Agency, 1400 Independence Ave., Stop 0801, Room 3053 South Building, Washington, DC 20250-0801.

(a) The first section will contain general information, including, as applicable:

(1) The applicant's name, address or primary business location, phone number, and e-mail address;

(2) The type of submission (see § 400.704);

(3) A statement of whether the applicant is requesting:

(i) Reinsurance, which includes risk subsidy and A&O subsidy;

(ii) Costs for reimbursement for research and development; or

(iii) Estimated costs for reimbursement for maintenance.

(4) The proposed agricultural commodities, including types, varieties, and practices covered by the submission;

(5) The crop and reinsurance years in which the submission is proposed to be available for purchase by producers;

(6) The proposed sales closing date;

(7) The proposed duration and scope of the plan of insurance;

(8) A marketing plan;

(9) Any known or anticipated future expansion plans;

(10) Identification, including names, addresses, telephone numbers, and e-mail addresses, of the persons responsible for:

(i) Addressing questions regarding the policy, underwriting rules and procedures, rate and price methodologies, data processing and record keeping requirements, and any other questions that may arise in administering the program after it is approved; and

(ii) Annual reviews to ensure compliance with all requirements of the Act, this subpart, and any agreements executed between the applicant and FCIC.

(11) A statement whether the submission will be filed with the applicable office responsible for regulating insurance in each state proposed for insurance coverage, and, if not, reasons why the submission will not be filed for review.

(b) The second section must contain the benefits of the plan, including, as

applicable, a statement about the plan that demonstrates:

(1) How the submission offers coverage or other benefits not currently available from existing public and private programs.

(2) The demand for the submission, which must be supported by information from market research, producers or producer groups, agents, lending institutions, and other interested parties that provide verifiable evidence of demand; and

(3) How the submission meets public policy goals and objectives consistent with the Act and other laws, as well as policy goals supported by USDA and the Federal Government.

(c) The third section must contain the policy, including, as applicable:

(1) If the submission involves a new insurance policy or plan of insurance:

(i) All applicable policy provisions; and,

(ii) A list and description of any additional coverage that may be elected by the insured, including how such coverage may be obtained.

(2) If the submission involves a change to a previously approved policy, plan of insurance, or rates of premium, the proposed revisions, rationale for each change, data and analysis supporting each change, the impact of each change, and the impact of all changes in aggregate.

(d) The fourth section must contain the information related to the marketing of the policy or plan of insurance, including, as applicable:

(1) A list of states and counties where the submission is proposed to be offered;

(2) The amount of commodity (acres, head, board feet, etc.), the amount of production, and the value of each agricultural commodity proposed to be covered in each proposed county and state;

(3) The expected liability and premium for each proposed county and state;

(4) If available, any insurance experience for each year and in each proposed county and state in which the policy has been previously offered for sale including an evaluation of the policy's performance and, if data are available, a comparison with other similar insurance policies reinsured under the Act; and

(5) The projected frequency and severity of loss if the proposed submission is approved.

(e) The fifth section must contain the information related to the underwriting of the submission, including, as applicable:

(1) A sample of each document or form that will be used to present and sell the product;

(2) Detailed rules for determining insurance eligibility, including all producer reporting requirements;

(3) Relevant dates, if not included in the proposed policy;

(4) Detailed examples of the data and calculations needed to establish the insurance guarantee, liability, and premium per acre or other unit of measure, including worksheets that provide the calculations in sufficient detail and in the same order as presented in the policy to allow verification that the premiums charged for the coverage are consistent with policy provisions;

(5) A detailed example of calculations used to determine a claim for indemnity for each unique situation in which a loss may be payable;

(6) A detailed description of the causes of loss covered by the policy or plan of insurance and any causes of loss excluded; and

(7) Any statements to be included in the actuarial documents.

(f) The sixth section must contain the information related to prices and the rates of premium, including, as applicable:

(1) A list of all assumptions made in the premium rating and commodity pricing methodologies, and the basis for these assumptions;

(2) A detailed description of the pricing and rating methodologies, including supporting documentation, all mathematical formulas, equations, and data sources used in determining rates and prices and an explanation of premium components that detail how rates were determined for each component, that demonstrate the rate is appropriate;

(3) An example of a rate calculation and an example of a price calculation;

(4) A discussion of the reliability of the data; and

(5) An analysis of the results of simulations or modeling showing the performance of proposed rates and commodity prices, as applicable, based on one or more of the following (Such simulations must use all years of experience available to the applicant):

(i) A recalculation of total premium and losses compared to a similar or comparable insurance plan offered under the authority of the Act with modifications, as needed, to represent the components of the submission;

(ii) A simulation based on the probability distributions used to develop the rates and commodity prices, as applicable, including sensitivity tests that demonstrate price or yield

extremes, and the impact of inappropriate assumptions; or

(iii) Any other comparable simulation that provides results indicating both aggregate and individual performance of the submission under various scenarios depicting good and poor actuarial experience.

(g) The seventh section must contain an evaluation and certification from an accredited associate or fellow of the Casualty Actuarial Society, or other similarly qualified professional, that certifies the submission is actuarially appropriate and consistent with appropriate insurance principles and practices.

(h) The eighth section must contain all forms applicable to the submission, including:

(1) An application for insurance and procedures for accepting the application; and

(2) All applicable policy forms, instructions and procedures that are necessary to establish the amounts of coverage or loss.

(i) The ninth section must contain the following:

(1) A statement agreeing that sales will be deferred until the next applicable sales closing date if policy information, forms, premium rates, prices, any automated premium calculator, and other related information or documents are not made available to all approved insurance providers:

(i) For a new submission, at least 60 days prior to the earliest sales closing date specified in the submission; or

(ii) For a revised submission, at least 60 days prior to the earliest contract change date specified in the submission;

(2) An explanation of any provision of the policy not authorized under the Act and identification of the portion of the rate of premium due to these provisions;

(3) Agent and loss adjuster training plans; and

(4) A certification from the applicant's legal counsel that the submission meets and complies with all requirements of the Act, applicable regulations, and any reinsurance agreement.

(j) The tenth section must contain the documents that demonstrate the submission complies in all respects with the standards established for processing and acceptance of data as specified in the FCIC Data Acceptance System Handbook (Manual 13), unless other arrangements have been made with RMA. This handbook is available from the Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133-4676 or on the FCIC web site (<http://www.rma.usda.gov/data/#m13>).

(k) The eleventh section must contain the information related to a request for reimbursement of research and development costs, and maintenance costs, as applicable, in accordance with § 400.712.

(l) The twelfth section must contain executed certification statements in accordance with the following:

(1) “[Applicant’s Name] hereby claim that the amounts set forth in this section and § 400.712 are correct and due and owing to {Applicant’s Name} by FCIC under the Federal Crop Insurance Act.”

(2) “[{Applicant Name}] understands that, in addition to criminal fines and imprisonment, the submission of false or fraudulent statements or claims may result in civil and administrative sanctions.”

§ 400.706 Review of submission.

(a) Prior to providing any submission, including a new submission, a resubmission, or a change to a previously approved submission, to the Board for its review, RMA will:

(1) Review the submission for completeness to determine if all necessary and appropriate documentation is included in accordance with § 400.705;

(2) Review the submission to determine whether the documentation is of a level of quality to conduct a meaningful review by the Board;

(3) If the submission is determined to be complete and the documentation of sufficient quality to permit a meaningful review, the submission will be considered to have been submitted to the Board for approval or disapproval. The date that FCIC determines that the submission is complete, as notified to the applicant, will be the date that the time frame for approval or disapproval by the Board begins;

(4) Return to the applicant any submission lacking any of the information required in § 400.705, or with documentation that is of insufficient quality to permit a meaningful review (such submission will not be considered as provided to the Board for the purpose of commencing the period by which the submission must be approved or disapproved by the Board. If the submission is resubmitted, it will be considered a new submission.);

(b) When FCIC determines that the submission is complete and the documentation of sufficient quality to permit a meaningful review, it will forward the submission to the Board for consideration for approval or disapproval.

(c) During the consideration process, the Board will:

(1) For all new submissions or significant changes to previously approved submissions, contract with five independent persons with underwriting or actuarial experience to review the submission:

(i) Of the five reviewers, no more than one will be employed by the Federal Government, and none may be employed by any approved insurance provider or their representatives; and

(ii) The reviewers will each provide their assessment of whether the submission protects the interests of agricultural producers and taxpayers, is actuarially appropriate, follows appropriate insurance principles, meets the requirements of the Act, does not contain excessive risks, follows sound, reasonable, and appropriate underwriting principles, as well as other items the Board may deem necessary;

(2) For all submissions:

(i) Request review by FCIC to determine whether the submission protects the interests of agricultural producers and taxpayers, is actuarially appropriate, follows appropriate insurance principles, meets the requirements of the Act, does not contain excessive risks, is consistent with USDA’s public policy goals, does not increase or shift risk to any other FCIC reinsured policy, can be administered and delivered efficiently and effectively, and meets the standards pursuant to § 400.712 for reimbursement of research and development costs and maintenance costs, if requested, and determine whether the requested amount of government reinsurance, risk subsidy, and administrative and operating subsidies is reasonable and appropriate for the type of coverage provided by the policy submission; and

(ii) Seek review from the Office of the General Counsel (OGC) to determine whether the interests of producers are adequately protected and if the submission conforms to the requirements of the Act.

(3) Render a decision to approve or give notice of an intent to disapprove within 90 days after the date the submission is considered submitted to the Board in accordance with paragraph (a)(3) of this section, unless the applicant and Board agree to a time delay in accordance with paragraph (h) of this section.

(d) All comments and evaluations will be forwarded to the Board by a date determined to allow the Board adequate time for review.

(e) The Board will consider all comments, evaluations, and recommendations in its review process. Prior to making a decision, the Board may request additional information

from RMA, OGC, the independent reviewers, or the applicant.

(f) The Board may disapprove a submission if it determines that:

(1) The interests of producers are not protected;

(2) The premium rates are not actuarially appropriate;

(3) The submission does not conform to sound insurance and underwriting principles;

(4) The risks associated with the submission are excessive; or

(5) There is insufficient time before the submission would become effective under section 508(h) of the Act for the Board to make an informed decision with respect to whether the interests of producers are protected, the premium rates are actuarially appropriate, or the risks associated with the submission are excessive.

(g) If the Board intends to disapprove the submission, the applicant will be notified in writing at least 30 days prior to the Board taking such action. The Board will provide the applicant with a written explanation for the intent to disapprove the submission.

(h) An applicant may request, at any time, a time delay before the Board provides a notice of intent to disapprove the submission. The Board is not required to agree to such an extension.

(1) The applicant understands that any requested time delay will not be limited in the length time or the number of delays. However, delays may make implementation of the submission for the targeted crop year impractical or impossible.

(2) The time period during which the Board must make a decision to approve or disapprove the submission is not in effect during any time delay requested by the applicant.

(3) The Board and the applicant must agree to a time period in which the Board must make its decision to approve or disapprove after the expiration of any requested time delay.

(i) The applicant may withdraw a submission at any time by written request to the Board. A withdrawn submission that is resubmitted will result in the submission being deemed a new submission for the purposes of determining the amount of time that the Board must act on such submission.

(j) Prior to any Board action taken or after the Board has provided formal notice of its intent to disapprove all or part of a submission:

(1) Modification can occur in writing or orally prior to the Board providing notice of its intent to disapprove all or part of a submission.

(2) After formal notice of intent to disapprove all or part of a submission

has been provided by the Board, the applicant must provide written to the Board that the submission will be modified not later than 30 days after the Board provided such notice. Except as provided in paragraph (j)(5) of this section, the applicant must also include the date that the modification will be provided to the Board.

(3) If the modification is in direct response to reviewer comments, the Board may act on the modification immediately or seek further review within the 30 day time period allowed.

(4) The Board will approve or disapprove a modified submission not later than 30 days after receiving a modified submission from the applicant, unless the applicant and the Board agree to a time delay. If a time delay is agreed upon the time period during which the Board must act on the modified submission will not be in effect during the delay.

(5) The Board will disapprove a modified submission if:

(i) All causes for disapproval stated by the Board in its notification of its intent to disapprove the submission are not satisfactorily addressed;

(ii) Insufficient time is available for review of the modified submission to determine whether all causes for disapproval have been satisfactorily addressed; or

(iii) If modification is so substantial that the Board determines that additional independent review is required and a time delay can not be agreed to allow for such review.

(k) When the applicant is notified of the Board's intent to disapprove and the submission is not revised or withdrawn, the Board will provide written notification to the applicant that the submission has been disapproved no less than 30 days after the date that the notice of intent to disapprove was provided to the applicant.

(l) If the Board fails to take action on a new submission within the prescribed 90 day period in paragraph (c)(3) of this section, or within the time period in accordance with paragraph (h)(3) of this section after receiving the revised submission, such submission will be deemed approved by the Board for the initial reinsurance year designated for the submission. The Board must approve the submission for it to be available for any subsequent reinsurance year.

§ 400.707 Presentation to the Board for approval or disapproval.

(a) The Board will inform the applicant of the date, time, and place of the Board meeting.

(b) The applicant will be given the opportunity and is encouraged to present the submission to the Board in person. The applicant must confirm, in writing, whether the applicant will present the submission to the Board.

(c) If the applicant elects, at any time, not to present the submission to the Board, the Board will make its decision based on the submission and the reviews provided in accordance with § 400.706(c).

§ 400.708 Approved submission.

(a) After a submission is approved by the Board, and prior to it being made available for sale to producers, the following items, as applicable, must be completed:

(1) If the Board requires, an agreement between the applicant and FCIC that specifies the responsibilities of each with respect to the implementation, delivery and oversight of the submission, including the disposition of property rights for the policy; and

(2) A reinsurance agreement if terms and conditions differ from the Standard Reinsurance Agreement.

(b) A submission approved by the Board under this subpart will be made available to all approved insurance providers under the same reinsurance and subsidy terms and conditions as received by the applicant.

(c) Any solicitation, sales, marketing, or advertising of the approved submission by the applicant before FCIC has made the submission and related materials available to all interested parties through its official issuance system will result in the denial of reinsurance, risk subsidy, and A&O subsidy for those policies affected.

§ 400.709 Roles and responsibilities.

(a) With respect to the applicant:

(1) The applicant is responsible for:

(i) Preparing and ensuring that all policy documents, rates of premium, and supporting materials, including actuarial materials, are submitted to FCIC in the form approved by the Board;

(ii) Except as provided in § 400.712(k)(2), annually updating and providing maintenance changes no later than 180 days prior to the earliest sales closing date for the commodity in all counties or states in which the policy or plan of insurance is sold and;

(iii) Addressing responses to procedural issues, questions, problems or clarifications in regard to a policy or plan of insurance (all such resolutions will be communicated to all approved insurance providers through FCIC's official issuance system.);

(2) Only the applicant may make changes to the policy, plan of insurance,

or rates of premium approved by the Board (Any changes, both non-significant and significant, must be submitted to FCIC no later than 180 days prior to the earliest sales closing date for the commodity in all counties or states in which the policy or plan of insurance is sold. Significant changes must be submitted to the Board for review in accordance with this subpart and will be considered as a new submission.);

(3) Except as provided in paragraph (a)(4) of this section, the applicant is solely liable for any mistakes, errors, or flaws in the submitted policy, plan of insurance, their related materials, or the rates of premium that have been approved by the Board unless the policy or plan of insurance is transferred to FCIC in accordance with § 400.712(k)(2), the applicant remains liable for any mistakes, errors, or flaws that occurred prior to the transfer of the policy or plan of insurance;

(4) If the mistake, error, or flaw in the policy, plan of insurance, their related materials, or the rates of premium is discovered not less than 45 days prior to the cancellation or termination date for the policy or plan of insurance, the applicant may request in writing that FCIC withdraw the approved policy, plan of insurance, or rates of premium:

(i) Such request must state the discovered mistake, error, or flaw in the policy, plan of insurance, or rates of premium, and the expected impact on the program; and

(ii) For all timely received requests for withdrawal, no liability will attach to such policies, plans of insurance, or rates of premium that have been withdrawn and no producer, approved insurance provider, or any other person will have a right of action against the applicant; and

(5) Notwithstanding the policy provisions regarding cancellation, any policy, plan of insurance, or rates of premium that have been timely withdrawn are deemed canceled and applications for insurance are not accepted as of the date that FCIC publishes the notice of withdrawal on its website at www.act.fcic.usda.gov. Producers will have the option of selecting any other policy or plan of insurance authorized under the Act that is available in their area by the sales closing date for such policy or plan of insurance.

(6) Failure of the applicant to perform the applicant's responsibilities may result in the denial of reinsurance for the policy or plan of insurance.

(b) With respect to FCIC:

(1) FCIC is responsible for:

(i) Ensuring that all approved insurance providers receive the approved policy or plan of insurance, and related materials, for sale to producers in a timely manner (All such information shall be communicated to all approved insurance providers through FCIC's official issuance system.);

(ii) Ensuring that all approved insurance providers receive reinsurance under the same terms and conditions as the applicant (approved insurance providers should contact FCIC to obtain and execute a copy of the reinsurance agreement) if required;

(iii) Conducting the best review of the submission possible in the time allowed; and

(iv) Reviewing the activities of approved insurance providers, agents, loss adjusters, and producers to ensure that they are in accordance with the terms of the policy or plan of insurance, the reinsurance agreement, and all applicable procedures;

(2) FCIC will not be liable for any mistakes, errors, or flaws in the policy, plan of insurance, their related materials, or the rates of premium and no cause of action will exist against FCIC as a result of such mistake, error, or flaw in a submission submitted under this subpart;

(3) If at any time prior to the cancellation or termination date, FCIC discovers that there is a mistake, error, or flaw in the policy, plan of insurance, their related materials, or the rates of premium that results in over or under insurance, FCIC will deny reinsurance to such policy or plan of insurance:

(4) If reinsurance is denied under paragraph (b)(3) of this section, the approved insurance provider will have the option of:

(i) Selling and servicing the policy or plan of insurance at its own risk and without any subsidy; or

(ii) Canceling the policy or plan of insurance in accordance with its terms; and

(5) If the applicant transfers the policy or plan of insurance to FCIC in accordance with § 400.712 (k)(2), FCIC will assume the liability for any mistakes, errors, or flaws that occur after the policy or plan insurance as been transferred and FCIC is in control of maintenance.

§ 400.710 Preemption and premium taxation.

A policy or plan of insurance that is approved by the Board for FCIC reinsurance is preempted from state and local taxation.

§ 400.711 Right of review, modification, and the withdrawal of reinsurance.

At any time after approval, the Board may review any policy, plan of insurance, related materials, and rates of premium approved under this subpart and request additional information to determine whether the policy, plan of insurance, related materials, and rates of premium comply with statutory or regulatory changes or court orders, are still actuarially appropriate, and protect program integrity and the interests of producers. The Board will notify the applicant of any problem or issue that may arise and allow the applicant an opportunity to make any needed change. The Board may deny reinsurance for the applicable policy, plan of insurance or rate of premium if:

(a) The applicant fails to perform their responsibilities under § 400.709; or

(b) If the applicant does not satisfactorily provide materials or resolve any issue so that necessary changes can be made prior to the earliest contract change date.

§ 400.712 Research and development reimbursement, maintenance reimbursement, and user fees.

(a) Submissions approved by the Board for reinsurance under section 508(h) of the Act may be eligible for a one time payment of research and development costs and maintenance costs for up to four reinsurance years, as determined by the Board after the date such costs have been approved by the Board. Reimbursements made under this section will be considered as payment in full for research, development, and maintenance, as applicable, for any policy or plan of insurance and any property rights to the policy or plan of insurance.

(b) For submissions submitted to the Board for reinsurance after publication of this subpart, an estimate of a request for reimbursement of research and development costs and maintenance costs, as applicable, must be included with the original submission to the Board in accordance with this section. These estimates will only be used by FCIC for the purpose of tracking potential expenditures and will not provided a basis for making any reimbursements under this section. Documentation of actual costs allowed under this section will be used to determine any reimbursement.

(c) For a submission approved by the Board, or submitted to the Board, prior to publication of this subpart, a request for reimbursement for research and development costs and estimated maintenance costs must be received within 60 days following publication of

this subpart or approval of the submission by the Board. This request should be sent to the Deputy Administrator, Research and Development (or any successor), Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133-4676, and also provide one identical copy of each submission to the Administrator, Risk Management Agency, 1400 Independence Ave., Stop 0801, Room 3053 South Building, Washington, D.C. 20250-0801.

(d) To be eligible for any reimbursement under this section, FCIC must determine that a submission is marketable.

(e) To be considered for reimbursement in any fiscal year, complete and final requests for research and development costs and maintenance costs, as applicable, must be received by FCIC not later than August 1. For 2001 fiscal year only, FCIC may consider reimbursement for research and development costs on approved submissions for any request received by September 1, 2001. Given the limitation on funds, regardless of when the request is received, no payment will be made prior to September 15 of the applicable fiscal year.

(f) There are limited funds available on an annual fiscal year basis as contained in the Act. Therefore, requests for reimbursement will not be considered in the order in which they are received. Consistent with paragraphs (g), (h), (i), (j), and (l) of this section, if all applicants' requests for reimbursement of research and development costs and maintenance costs in any fiscal year:

(1) Do not exceed the maximum amount authorized by law, the applicants may receive the full amount of reimbursement authorized under these subsections.

(2) Exceed the amount authorized by law, each applicant's reimbursement will be determined by dividing the total amount of each individual applicants' reimbursable costs authorized in paragraphs (g), (h), (i), (j), and (l) by the total amount of the aggregate of all applicants' reimbursable costs authorized in paragraphs (g), (h), (i), (j), and (l) for that year and multiplying the result by the amount of reimbursement authorized under the Act.

(g) The amount of reimbursement for research and development costs and maintenance costs, as applicable, will be determined based on the amount of reimbursement authorized under paragraph (f) of this section, adjusted for the complexity of the policy, plan of insurance, or rates of premium, as

determined by FCIC, and the size of the area in which the policy, plan of insurance, or rates of premium may be offered.

(1) Policies or plans of insurance that offer new and innovative coverages that are not currently available will be eligible for a higher reimbursement than policies or plans of insurance that are, or have components that are, based on existing policies or plans of insurance.

(2) Policies or plans of insurance that offer new premium rating or market price methodologies will be eligible for a higher reimbursement than policies or plans of insurance that use existing premium rating or market price methodologies.

(3) Policies or plans of insurance that cover new commodities that are not otherwise covered by crop insurance or that offer innovative coverage and original policy language will be eligible for a higher reimbursement than policies or plans of insurance for commodities for which insurance is currently available.

(4) Policies or plans of insurance that may be offered for sale nationwide or in large geographical regions will be eligible for higher reimbursement than those that are applicable to only a few counties or states or a small geographical region.

(5) Any reimbursement under this subpart will be scored as follows:

(i) Complexity scores:

(A) Basic or Common Provisions:

(1) Uses existing policies or plans of insurance: 0.05

(2) Contains modifications to existing policies or plans of insurance: 0.10

(3) Original (See paragraph (g)(3) of this section): 0.20

(B) Crop Provisions and Special Provisions:

(1) Uses existing policies or plans of insurance: 0.05

(2) Contains modifications to existing policies or plans of insurance: 0.10

(3) Original (See paragraph (g)(3) of this section): 0.20

(C) Market prices:

(1) Uses existing policies or plans of insurance: 0.05

(2) Contains modifications to existing policies or plans of insurance: 0.10

(3) Original (See paragraph (g)(3) of this section): 0.20

(D) Rates of Premium:

(1) Uses existing policies or plans of insurance: 0.05

(2) Contains modifications to existing policies or plans of insurance: 0.10

(3) Original (See paragraph (g)(3) of this section): 0.20

(E) Underwriting:

(1) Uses existing policies or plans of insurance: 0.05

(2) Contains modifications to existing policies or plans of insurance: 0.10

(3) Original (See paragraph (g)(3) of this section): 0.20

(ii) Geographic scope scores:

(A) Potential national availability: 0.10

(B) Potential regional, state or county availability: 0.05

(6) In accordance with paragraph (e) of this section, those policies or plans of insurance that receive a summed total score for both complexity and geographic scope that is:

(i) Equal to or greater than 0.6 may receive the full amount of reimbursement approved by the Board under paragraphs (h), (i) or (j) of this section;

(ii) Greater than 0.25 but lower than 0.60 will receive a reimbursement that is not greater than 75 percent of the full amount of reimbursement approved by the Board under paragraphs (h), (i) or (j) of this section; and

(iii) Equal to or less than 0.25 will receive a reimbursement that is not greater than 50 percent of the full amount of reimbursement approved by the Board under paragraphs (h), (i) or (j) of this section.

(h) For those submissions that were approved by the Board prior to the date of publication of this subpart, reimbursement for research and development costs will be determined in accordance with paragraph (i) of this section or by multiplying the average number of policies earning premium each crop year since inception of the policy or plan of insurance by \$7.00 and multiplying the result by the complexity and scope score from paragraph (g) of this section.

(i) For those submissions submitted to the Board prior to the date of publication of this subpart but not yet approved, or submitted to the Board for approval after the date of publication of this part, research and development costs must be supported by itemized statements and supporting documentation (copies of contracts, billing statements, time sheets, travel vouchers, accounting ledgers, etc.). Actual costs submitted will be examined for reasonableness and may be adjusted at the sole discretion of the Board.

(1) Allowable research and development expense items (directly related to research and development of the submission only) may include the following:

(i) Straight-time hourly wage, exclusive of bonuses, overtime pay, or shift differentials (One line per employee, include job title, total hours, and total dollars. Compensation

amounts will be compared with the Occupational Employment Statistics Survey, published each January by the U.S. Department of Labor, Bureau of Labor Statistics);

(ii) Benefit cost per employee (Benefit costs are considered overhead and will be compared with the Employment Cost Index Annual Employer Cost Survey published each March by the U.S. Department of Labor, Bureau of Labor Statistics.);

(iii) Contracted expenses (include a copy of the contract, billing statements, accounting records, etc.);

(iv) Professional fees (include the job title, straight-time hourly wage, total hours, and total dollars);

(v) Travel and transportation (One line per event, include the job title, destination, purpose of travel, lodging cost, mileage, air or other identified transportation costs, food and miscellaneous expenses, other costs, and the total cost);

(vi) Software and computer programming developed specifically to determine appropriate rates, prices, or coverage amounts (Identify the item, include the purpose, and provide receipts or contract or straight-time hourly wage, hours, and total cost. Software developed to calculate premiums or losses, or development of software to send or receive data between the producer, agent, approved insurance provider or RMA or such other similar software may not be included as an allowable cost.);

(vii) Miscellaneous expenses such as postage, telephone, express mail, and printing (Identify the item, cost per unit, number of items, and total dollars);

(2) The following expenses are specifically not eligible for research and development cost reimbursement:

(i) Copyright or patent fees;

(ii) Training costs;

(iii) State filing fees and expenses;

(iv) Normal ongoing administrative expenses;

(v) Paid or incurred losses;

(vi) Loss adjustment expenses;

(vii) Sales commission;

(viii) Marketing costs;

(ix) Indirect overhead costs;

(x) Lobbying costs;

(xi) Product or applicant liability resulting from the research, development, preparation or marketing of the policy;

(xii) Copyright infringement claims resulting from the research, development, preparation or marketing of the policy;

(xiii) Costs of making program changes as a result of case or statutory law affecting the policy; and

(xiv) Maintenance costs associated with the submission.

(j) Requests for reimbursement of maintenance costs for submissions approved after publication of this subpart must be supported by itemized statements and supporting documentary evidence for each reinsurance year in the maintenance period. For submissions approved prior to publication of this subpart, the applicant may provide itemized statements and supporting documentary evidence or may request to receive not more than 15 percent of the amount of reimbursement for research and development costs, as determined in accordance with § 400.712, for the first reinsurance year in the maintenance period. For all subsequent reinsurance years, itemized and supporting documentary evidence must be provided. Actual costs submitted will be examined for reasonableness and may be adjusted at the sole discretion of the Board.

(1) Maintenance costs for the following activities may be reimbursed:

(i) Expansion of the original submission to cover additional commodities;

(ii) Expansion of the original submission into additional counties or states;

(iii) Reasonable and required modifications to the policy and any related materials;

(iv) Adjustment to premium rates and commodity prices as necessary or required; and

(v) Other costs associated with maintaining the policy, as determined by the Board.

(2) [Reserved]

(k) Not later than six months prior to the end of the last reinsurance year in which a maintenance reimbursement will be paid, as approved by the Board, the applicant must notify FCIC regarding its election of the treatment of the policy or plan of insurance for subsequent reinsurance years.

(1) The applicant must notify FCIC whether it intends to:

(i) Continue to maintain the policy or plan of insurance and charge a user fee, as approved by the Board, to approved insurance providers for all policies earning premium to cover maintenance expenses. It is the sole responsibility of the applicant to collect such fees from the approved insurance providers and any indebtedness for such fees must be resolved by the applicant and approved insurance provider. Applicants may request that FCIC provide the number of policies sold by each approved insurance provider. Such information will be provided not later than 90 days after such request is made or not later than 90 days after the requisite

information has been provided to FCIC by the approved insurance provider, which ever is later; or

(ii) Transfer responsibility for maintenance to FCIC.

(2) If the applicant elects to:

(i) Transfer the policy or plan of insurance to FCIC, FCIC may, at its sole discretion, elect to withdraw the availability of the policy or plan of insurance or continue to maintain the policy or plan of insurance; or

(ii) Continue to maintain the policy or plan of insurance, at the time of the election, the applicant must submit a request for approval of the user fee by the Board.

(3) Requests for approval of the user fee must be accompanied by written documentation to support that the amount requested will only cover maintenance costs.

(4) The Board will approve the amount of user fee that is payable to the applicant by approved insurance providers unless the Board determines that the user fee charged:

(i) Is unreasonable in relation to the maintenance costs associated with the policy or plan of insurance; or

(ii) Unnecessarily inhibits the use of the policy or plan of insurance by other approved insurance providers.

(5) Reasonableness of the user fees will be determined by the Board based on a comparison with the amount of reimbursement for maintenance previously received, the number of policies, the number of approved insurance providers, and the expected total amount of user fees to be received in any reinsurance year.

(6) A user fee unnecessarily inhibits the use of a policy or plan of insurance if it is so high that other approved insurance providers are unable to pay such fees because of the volume of business currently underwritten by the approved insurance provider.

(7) The user fee charged to each approved insurance provider will be considered payment in full for the use of such policy, plan of insurance or rate of premium for the reinsurance year in which payment is made.

(l) The Board may consider information from the Equal Access to Justice Act, 5 U.S.C. 504, the Bureau of Labor Statistic's Occupational Employment Statistics Survey, the Bureau of Labor Statistic's Employment Cost Index, and any other information determined applicable by the Board, in making a determination whether to approve a submission for reimbursement of research, development, or maintenance costs under this section or the amount of reimbursement.

(m) For purposes of this section, rights to, or obligations of, research and development reimbursement, maintenance cost reimbursement, or user fees cannot be transferred from any individual or entity unless specifically approved in writing by the Board.

§ 400.713 Non-Reinsured supplemental (NRS) policy.

(a) The reinsured company must submit three copies of the new or revised NRS policy and related materials to the Deputy Administrator, Research and Development (or successor), Risk Management Agency, 6501 Beacon Drive, Stop 0812, Kansas City, MO 64133-4676 for review, approval or disapproval at least 90 days prior to the first sales closing date applicable to the policy reinsured by FCIC.

(b) FCIC will approve the NRS policy if it does not increase or shift risk to the underlying policy or plan of insurance reinsured by FCIC, affect any rights of the insured with respect to the underlying reinsured policy or plan of insurance, or cause disruption in the marketplace for products reinsured by FCIC. Marketplace disruption includes adversely affecting sales or administration of the underlying

reinsured policy, undermining producers' confidence in the Federal crop insurance program, decreasing the producer's willingness or ability to use Federally reinsured risk management products, or harming public perception of the Federal crop insurance program.

(c) Failure to timely submit the NRS policy to FCIC will result in the denial of reinsurance and subsidy for all policies reinsured by FCIC for which the insured has obtained the NRS policy.

Signed in Washington, D.C. on September 12, 2001.

Phyllis W. Honor,

Acting Manager, Federal Crop Insurance Corporation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

New Animal Drugs; Change of Sponsor; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 43 approved new animal drug applications (NADAs) and 16 approved abbreviated new animal drug applications (ANADAs) from Hoechst Roussel Vet to Intervet, Inc. Technical amendments are also being made. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective September 17, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010, has informed FDA that it has transferred ownership of, and all rights and interest in, the following NADAs and ANADAs to Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966.

NADA Number	Product Name
34-478	LASIX® Injection
34-621	LASIX® Tablets and Boluses
44-759	FLAVOMYCIN® Type A Medicated Article
45-188	LASIX® Packets
95-543	AMPROL HI-E®/FLAVOMYCIN®
95-547	AMPROL HI-E®/FLAVOMYCIN®/3-NITRO®
95-548	AMPROL®/3-NITRO®/FLAVOMYCIN®
95-549	AMPROL®/3-NITRO®/FLAVOMYCIN®
98-340	FLAVOMYCIN®/Monensin
98-341	FLAVOMYCIN®/3-NITRO®/COBAN®
101-628	FLAVOMYCIN®/3-NITRO®/ZOALENE®
101-629	FLAVOMYCIN®/ZOALENE®
102-380	LASIX® Syrup
104-494	PANACUR® 10% Suspension
111-278	PANACUR® Granules 22%
120-648	PANACUR®/SAFE-GUARD® Paste
121-473	PANACUR® Granules 22%
128-620	PANACUR®/SAFE-GUARD® 10% Suspension
130-185	FLAVOMYCIN®/Amprolium
130-661	FLAVOMYCIN®/CARB-O-SEP®
130-951	STENOROL® Type A Medicated Article
131-310	REGU-MATE® Solution
131-675	SAFE-GUARD® Type A Medicated Article
132-872	PANACUR®/SAFE-GUARD® 10% Paste
137-483	FLAVOMYCIN®/STENOROL®
137-600	SAFE-GUARD® Type A Medicated Article
138-612	FINAPLIX®-S; FINAPLIX®-H Implants
139-189	SAFE-GUARD® ENPROAL Feedblocks
139-473	STENOROL®/STAFAC®
140-339	FLAVOMYCIN®/NICARB®
140-340	STENOROL®/LINCOMIX®
140-533	STENOROL®/3-NITRO®/BMD®
140-584	STENOROL®/BMD®
140-824	STENOROL® Type A Medicated Article
140-843	MONTEBAN®/FLAVOMYCIN®/3-NITRO®
140-845	FLAVOMYCIN®/MONTEBAN®
140-897	REVALOR®-S; REVALOR®-G Implants