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FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Parts 2411 and 2417

Testimony by FLRA Employees and Production of Official Records in Legal Proceedings

AGENCY: Federal Labor Relations Authority.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Labor Relations Authority's (FLRA) rules by setting out procedures for requesters to follow when making demands on or requests to an employee of the FLRA, the General Counsel of the FLRA (General Counsel) or the Federal Service Impasses Panel (Panel) to produce official records or provide testimony relating to official information in connection with a civil legal proceeding in which the FLRA is not named as a party. The final rule establishes procedures to respond to such demands and requests in an orderly and consistent manner. The final rule promotes uniformity in decisions, protects confidential information, provides guidance to requesters, and reduces the potential for both inappropriate disclosures of official information and wasteful allocation of agency resources.

DATES: This final rule is effective March 19, 2009.

FOR FURTHER INFORMATION CONTACT: Rosa M. Koppel, Solicitor, Federal Labor Relations Authority, 1400 K Street, NW., Washington, DC 20424; (202) 218-7999; fax: (202) 343-1007; or e-mail rkoppel@flra.gov.

SUPPLEMENTARY INFORMATION: The FLRA is amending and relocating to a new Part 2417 what was § 2411.11. Section 2411.11 prohibited employees from producing documents or giving testimony in response to a subpoena or other request without the written

consent of the FLRA, the General Counsel or the Panel, as appropriate. Under § 2411.11, any employee served with a subpoena or request who was not given the requisite written consent was instructed to move to have the subpoena invalidated "on the ground that the evidence sought is privileged against disclosure by this rule." This approach incorrectly treated the regulations as though they created a privilege against disclosure.

The FLRA is amending the regulations to set out specific procedures that must be followed by persons who submit demands or requests for non-public FLRA information. The new Part 2417 also sets out factors that the FLRA will consider when deliberating on demands or requests for non-public FLRA information. Non-public information, as that term is used in this proposal, is information, confidential or otherwise, not available to the public pursuant to the Freedom of Information Act.

Responding to such demands and requests may result in a significant disruption of an FLRA employee's work schedule and possibly involve the FLRA in issues unrelated to its responsibilities. In order to resolve these problems, many agencies have issued regulations, similar to these new regulations, governing the circumstances and manner in which an employee may respond to demands for testimony or for the production of documents. The United States Supreme Court upheld this type of regulation in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

This rule applies to a range of matters in any civil legal proceeding in which the FLRA is not a named party. It also applies to former and current FLRA employees (as well as to FLRA consultants and advisors). Former FLRA employees are prohibited from testifying about specific matters for which they had responsibility during their active employment unless permitted to testify as provided in the regulations. They would not be prohibited from testifying about general matters unconnected with the specific FLRA matters for which they had responsibility.

This rule will ensure a more efficient use of the FLRA's resources, minimize the possibility of involving the FLRA in issues unrelated to its responsibilities, promote uniformity in responding to

such subpoenas and requests, and maintain the impartiality of the FLRA in matters that are in dispute between other parties. It will also serve the FLRA's interest in protecting sensitive, confidential, and privileged information and records that are generated in fulfillment of the FLRA's statutory responsibilities.

The charges for witnesses are the same as those provided in Federal courts; and the fees related to production of records are the same as those charged under the Freedom of Information Act. The charges for time spent by an employee to prepare for testimony and for searches, copying, and certification of records by the FLRA are authorized under 31 U.S.C. 9701, which permits an agency to charge for services or things of value that are provided by the agency.

This rule is internal and procedural rather than substantive. It does not create a right to obtain official records or the official testimony of an FLRA employee nor does it create any additional right or privilege not already available to FLRA to deny any demand or request for testimony or documents. Failure to comply with the procedures set out in these regulations would be a basis for denying a demand or request submitted to the FLRA.

On December 24, 2008, the FLRA published a proposed rule with request for comments that proposed to amend 5 CFR, chapter XIV (73 FR 79024). The FLRA received no comments during the 30 days allowed for public comment and this final rule makes no changes to the previously published proposed rule. See 73 FR 79024 for additional information concerning this amendment of 5 CFR, chapter XIV.

List of Subjects in 5 CFR Parts 2411 and 2417

Administrative practice and procedure; Government employees.

■ For the reasons stated in the preamble, the Federal Labor Relations Authority amends 5 CFR part 2411 and adds part 2417 as set forth below:

PART 2411—AVAILABILITY OF OFFICIAL INFORMATION

■ 1. The authority citation for part 2411 continues to read as follows:

Authority: 5 U.S.C. 552

§ 2411.11 [Removed]

- 2. Section 2411.11 is removed.

§ 2411.12 [Amended]

- 3. Section 2411.12 is redesignated as § 2411.11.
- 4. Part 2417 is added to read as follows:

PART 2417—TESTIMONY BY EMPLOYEES RELATING TO OFFICIAL INFORMATION AND PRODUCTION OF OFFICIAL RECORDS IN LEGAL PROCEEDINGS

Subpart A—General Provisions

Sec.

- 2417.101 Scope and purpose.
- 2417.102 Applicability.
- 2417.103 Definitions.

Subpart B—Demands or Requests for Testimony and Production of Documents

- 2417.201 General prohibition.
- 2417.202 Factors to consider.
- 2417.203 Filing requirements for litigants seeking documents or testimony.
- 2417.204 Where to submit a request.
- 2417.205 Processing of requests or demands.
- 2417.206 Final determinations.
- 2417.207 Restrictions that apply to testimony.
- 2417.208 Restrictions that apply to released records.
- 2417.209 Procedure when a decision is not made prior to the time a response is required.
- 2417.210 Procedure in the event of an adverse ruling.

Subpart C—Schedule of Fees

- 2417.301 Fees.

Subpart D—Penalties

- 2417.401 Penalties.

Authority: 5 U.S.C. 7105; 31 U.S.C. 9701; 44 U.S.C. 3101–3107.

Subpart A—General Provisions**§ 2417.101 Scope and purpose.**

(a) These regulations establish policy, assign responsibilities and prescribe procedures with respect to:

- (1) The production or disclosure of official information or records by employees, members, advisors, and consultants of the Federal Labor Relations Authority, the General Counsel of the Federal Labor Relations Authority or the Federal Service Impasses Panel; and
- (2) The testimony of current and former employees, members, advisors, and consultants of the Authority, the General Counsel or the Panel relating to official information, official duties or official records, in connection with civil federal or state litigation in which the Authority, the General Counsel or the Panel is not a party.

(b) The FLRA intends these provisions to:

- (1) Conserve the time of employees for conducting official business;
 - (2) Minimize the involvement of employees in issues unrelated to the mission of the FLRA;
 - (3) Maintain the impartiality of employees in disputes between private litigants; and
 - (4) Protect sensitive, confidential information and the deliberative processes of the FLRA.
- (c) In providing for these requirements, the FLRA does not waive the sovereign immunity of the United States.

(d) This part provides guidance for the internal operations of the FLRA. It does not create any right or benefit, substantive or procedural, that a party may rely upon in any legal proceeding against the United States.

§ 2417.102 Applicability.

This part applies to demands and requests to current and former employees, members, advisors, and consultants for factual or expert testimony relating to official information or official duties or for production of official records or information, in civil legal proceedings in which the Authority, the General Counsel or the Panel is not a named party. This part does not apply to:

- (a) Demands upon or requests for an employee to testify as to facts or events that are unrelated to his or her official duties or that are unrelated to the functions of the Authority, the General Counsel or the Panel;
- (b) Demands upon or requests for a former employee to testify as to matters in which the former employee was not directly or materially involved while at the Authority, the General Counsel or the Panel;
- (c) Requests for the release of records under the Freedom of Information Act, 5 U.S.C. 552, or the Privacy Act, 5 U.S.C. 552a;
- (d) Congressional demands and requests for testimony, records or information; or
- (e) Demands or requests for testimony, records or information by any Federal, state, or local agency in furtherance of an ongoing investigation of possible violations of criminal law.

§ 2417.103 Definitions.

The following definitions apply to this part.

- (a) *Demand* means an order, subpoena, or other command of a court or other competent authority for the production, disclosure, or release of records or for the appearance and

testimony of an employee in a civil legal proceeding.

(b) *Legal proceeding* means any matter before a court of law, administrative board or tribunal, commission, administrative law judge, hearing officer or other body that conducts a civil legal or administrative proceeding. Legal proceeding includes all phases of litigation.

(c) *Employee* means:

- (i) Any current or former employee or member of the Authority, the General Counsel or the Federal Service Impasses Panel;
- (ii) Any other individual hired through contractual agreement by or on behalf of the Authority or who has performed or is performing services under such an agreement for the Authority; and
- (iii) Any individual who served or is serving in any consulting or advisory capacity to the Authority whether formal or informal.

This definition does not include: Persons who are no longer employed by the Authority, the General Counsel or the Panel and who agree to testify about general matters, matters available to the public or matters with which they had no specific involvement or responsibility during their employment with the Authority, the General Counsel or the Panel.

(d) *Records or official records and information* means: All information in the custody and control of the Authority, the General Counsel or the Panel, relating to information in the custody and control thereof, or acquired by an employee while in the performance of his or her official duties or because of his or her official status, while the individual was employed by or on behalf of the Authority, the General Counsel or the Panel.

(e) *Request* means any informal request, by whatever method, for the production of records and information or for testimony which has not been ordered by a court or other competent authority.

(f) *Testimony* means any written or oral statements, including depositions, answers to interrogatories, affidavits, declarations, interviews, and statements made by an individual in connection with a legal proceeding.

Subpart B—Demands or Requests for Testimony and Production of Documents**§ 2417.201 General prohibition.**

No employee of the Authority, the General Counsel or the Panel may produce official records and information or provide any testimony relating to

official information in response to a demand or request without the prior, written approval of the Chairman of the FLRA or the Chairman's designee.

§ 2417.202 Factors the FLRA will consider.

The Chairman or the Chairman's designee, in his or her sole discretion, may grant an employee permission to testify on matters relating to official information, or produce official records and information, in response to a demand or request. Among the relevant factors that the Chairman may consider in making this decision are whether:

- (a) The purposes of this part are met;
- (b) Allowing such testimony or production of records would be necessary to prevent a miscarriage of justice;
- (c) Allowing such testimony or production of records would assist or hinder the FLRA in performing its statutory duties;
- (d) Allowing such testimony or production of records would be in the best interest of the FLRA;
- (e) The records or testimony can be obtained from other sources;
- (f) The demand or request is unduly burdensome or otherwise inappropriate under the applicable rules of discovery or the rules of procedure governing the case or matter in which the demand or request arose;
- (g) Disclosure would violate a statute, Executive Order or regulation;
- (h) Disclosure would reveal confidential, sensitive, or privileged information, trade secrets or similar, confidential or financial information, otherwise protected information, or information which would otherwise be inappropriate for release;
- (i) Disclosure would impede or interfere with an ongoing law enforcement investigation or proceeding, or compromise constitutional rights or national security interests;
- (j) Disclosure would result in the FLRA appearing to favor one litigant over another;
- (k) The request was served before the demand;
- (l) A substantial Government interest is implicated;
- (m) The demand or request is within the authority of the party making it;
- (n) The demand or request is sufficiently specific to be answered; and
- (o) Any other factor deemed relevant under the circumstances of the particular request.

§ 2417.203 Filing requirements for litigants seeking documents or testimony.

A litigant must comply with the following requirements when filing a

request for official records and information or testimony under part 2417. A request should be filed before a demand.

(a) The request must be in writing and must be submitted to the Office of the Solicitor.

(b) The written request must contain the following information:

- (1) The caption of the legal proceeding, docket number, and name and address of the court or other authority involved;
- (2) A copy of the complaint or equivalent document setting forth the assertions in the case and any other pleading or document necessary to show relevance;
- (3) A list of categories of records sought, a detailed description of how the information sought is relevant to the issues in the legal proceeding, and a specific description of the substance of the testimony or records sought;
- (4) A statement as to how the need for the information outweighs any need to maintain the confidentiality of the information and outweighs the burden on the FLRA to produce the records or provide testimony;
- (5) A statement indicating that the information sought is not available from another source, from other persons or entities or from the testimony of someone other than an employee, such as a retained expert;
- (6) If testimony is requested, the intended use of the testimony, and a showing that no document could be provided and used in lieu of testimony;
- (7) A description of all prior decisions, orders or pending motions in the case that bear upon the relevance of the requested records or testimony;
- (8) The name, address, and telephone number of counsel to each party in the case; and
- (9) An estimate of the amount of time that the requester and other parties will require for each employee for time spent by the employee to prepare for testimony, in travel, and for attendance in the legal proceeding.

(c) The Office of the Solicitor reserves the right to require additional information to complete the request where appropriate.

(d) The request should be submitted at least 30 days before the date that records or testimony is required. Requests submitted in less than 30 days before records or testimony is required must be accompanied by a written explanation stating the reasons for the late request and the reasons for expedited processing.

(e) Failure to cooperate in good faith to enable the FLRA to make an informed decision may serve as the basis for a

determination not to comply with the request.

(f) The request should state that the requester will provide a copy of the employee's statement free of charge and that the requester will permit the FLRA to have a representative present during the employee's testimony.

§ 2417.204 Where to submit a request.

(a) Requests or demands for official records or information or testimony under this part must be served on the Office of the Solicitor at the following address: Office of the Solicitor, Federal Labor Relations Authority, 1400 K Street, NW., Suite 201, Washington, DC 20424-0001; *telephone*: (202) 218-7999; *fax*: (202) 343-1007. The request must be sent by mail, fax, or e-mail and clearly marked "Part 2417 Request for Testimony or Official Records in Legal Proceedings."

(b) A person requesting public FLRA information and non-public FLRA information under this part may submit a combined request for both to the Office of the Solicitor. If a requester decides to submit a combined request under this section, the FLRA will process the combined request under this part and not under part 2411 (FOIA).

§ 2417.205 Consideration of requests or demands.

(a) After receiving service of a request or demand for testimony, the FLRA will review the request and, in accordance with the provisions of this part, determine whether, or under what conditions, to authorize the employee to testify on matters relating to official information and/or produce official records and information.

(b) Absent exigent circumstances, the FLRA will issue a determination within 30 days from the date the request is received.

(c) The FLRA may grant a waiver of any procedure described by this part where a waiver is considered necessary to promote a significant interest of the FLRA or the United States or for other good cause.

(d) *Certification (authentication) of copies of records.* The FLRA may certify that records are true copies in order to facilitate their use as evidence. If a requester seeks certification, the requester must request certified copies from the Solicitor at least 30 days before the date they will be needed.

§ 2417.206 Final determination.

The Chairman of the FLRA, or the Chairman's designee, makes the final determination on demands or requests to employees thereof for production of official records and information or

testimony in litigation in which the FLRA is not a party. All final determinations are within the sole discretion of the Chairman or the Chairman's designee. The Chairman or designee will notify the requester and, when appropriate, the court or other competent authority of the final determination, the reasons for the grant or denial of the request, and any conditions that may be imposed on the release of records or information, or on the testimony of an employee. This final determination exhausts administrative remedies for discovery of the information.

§ 2417.207 Restrictions that apply to testimony.

(a) Conditions or restrictions may be imposed on the testimony of employees including, for example:

- (1) Limiting the areas of testimony;
- (2) Requiring the requester and other parties to the legal proceeding to agree that the transcript of the testimony will be kept under seal;
- (3) Requiring that the transcript will be used or made available only in the particular legal proceeding for which testimony was requested. The requester may also be required to provide a copy of the transcript of testimony at the requester's expense.

(b) The employee's written declaration may be provided in lieu of testimony.

(c) If authorized to testify pursuant to this part, an employee may testify as to facts within his or her personal knowledge, but, unless specifically authorized to do so by the Chairman or the Chairman's designee, the employee shall not:

- (1) Disclose confidential or privileged information; or
- (2) For a current employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or the functions of the FLRA unless testimony is being given on behalf of the United States (*see* also 5 CFR 2635.805).

(d) The scheduling of an employee's testimony, including the amount of time that the employee will be made available for testimony, will be subject to the approval of the Chairman or the Chairman's designee.

§ 2417.208 Restrictions that apply to released records.

(a) The Chairman or the Chairman's designee may impose conditions or restrictions on the release of official records and information, including the requirement that parties to the proceeding obtain a protective order or execute a confidentiality agreement to

limit access and any further disclosure. The terms of the protective order or of a confidentiality agreement must be acceptable to the Chairman or the Chairman's designee. In cases where protective orders or confidentiality agreements have already been executed, the Chairman or the Chairman's designee may condition the release of official records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the Chairman or the Chairman's designee so determines, original records may be presented for examination in response to a request, but they may not be presented as evidence or otherwise used in a manner by which they could lose their identity as official records, nor may they be marked or altered. In lieu of the original records, certified copies may be presented for evidentiary purposes.

§ 2417.209 Procedure when a decision is not made prior to the time a response is required.

If a response to a demand or request is required before the Chairman or the Chairman's designee can make the determination referred to in § 2417.206, the Chairman or the Chairman's designee, when necessary, will provide the court or other competent authority with a copy of this part, inform the court or other competent authority that the request is being reviewed, provide an estimate as to when a decision will be made, and seek a stay of the demand or request pending a final determination.

§ 2417.210 Procedure in the event of an adverse ruling.

If the court or other competent authority fails to stay a demand or request, the employee upon whom the demand or request is made, unless otherwise advised by the Chairman or the Chairman's designee, will appear, if necessary, at the stated time and place, produce a copy of this part, state that the employee has been advised by counsel not to provide the requested testimony or produce documents, and respectfully decline to comply with the demand or request, citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

Subpart C—Schedule of Fees

§ 2417.301 Fees.

(a) *Generally.* The Chairman or the Chairman's designee may condition the production of records or appearance for testimony upon advance payment of a reasonable estimate of the costs thereto.

(b) *Fees for records.* Fees for producing records will include fees for

searching, reviewing, and duplicating records, costs of employee time spent in reviewing the request, and expenses generated by materials and equipment used to search for, produce, and copy the responsive information. These fees and costs will be calculated and charged as are like fees and costs arising from requests made pursuant to the Freedom of Information Act regulations in Part 2411.

(c) *Witness fees.* Fees for attendance by a witness will include fees, expenses, and allowances prescribed by the court's rules. If no such fees are prescribed, witness fees will be determined based upon the rule of the Federal district court closest to the location where the witness will appear and on 28 U.S.C. 1821, as applicable. Such fees will include cost of time spent by the witness to prepare for testimony, in travel and for attendance in the legal proceeding, plus travel costs.

(d) *Payment of fees.* A requester must pay witness fees for current employees and any record certification fees by submitting to the Office of the Solicitor a check or money order for the appropriate amount made payable to the Treasury of the United States. In the case of testimony of former employees, the requester must pay applicable fees directly to the former employee in accordance with 28 U.S.C. 1821 or other applicable statutes.

(e) *Waiver or reduction of fees.* The Chairman or the Chairman's designee, in his or her sole discretion, may, upon a showing of reasonable cause, waive or reduce any fees in connection with the testimony, production, or certification of records.

(f) *De minimis fees.* Fees will not be assessed if the total charge would be \$10.00 or less.

Subpart D—Penalties

§ 2417.401 Penalties.

(a) An employee who discloses official records or information or gives testimony relating to official information, except as expressly authorized by the Chairman or the Chairman's designee, or as ordered by a Federal court after the FLRA has had the opportunity to be heard, may face the penalties provided in 18 U.S.C. 641 and other applicable laws. Additionally, former employees are subject to the restrictions and penalties of 18 U.S.C. 207 and 216.

(b) A current employee who testifies or produces official records and information in violation of this part may be subject to disciplinary action.

Dated: March 11, 2009.

Carol Waller Pope,

Acting Chairman.

[FR Doc. E9-5694 Filed 3-18-09; 8:45 am]

BILLING CODE 6727-01-P

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Parts 400, 407, 457

RIN 0563-AB73

General Administrative Regulations; Administrative Remedies for Non-Compliance; Correcting Amendments

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule; correcting amendment.

SUMMARY: This document contains correcting amendments to the final regulations that were published December 18, 2008 (73 FR 76868-76891). These regulations pertain to Administrative Remedies for Non-Compliance and provide clarification of existing remedies.

DATES: *Effective Date:* March 19, 2009.

FOR FURTHER INFORMATION CONTACT: Cynthia Simpson, Director, Appeals, Litigation and Legal Liaison Staff, Risk Management Agency, United States Department of Agriculture, 1400 Independence Avenue, SW., Room 6603, Stop 0806, Washington, DC 20250, telephone (202) 720-0642.

SUPPLEMENTARY INFORMATION:

Background

The final regulation that is the subject of these correcting amendments was intended to add additional administrative remedies that are available as a result of the enactment of section 515(h) of the Federal Crop Insurance Act (Act) (7 U.S.C. 1515(h)), make such other changes as are necessary to implement the provisions of section 515(h) of the Act, and to clarify existing administrative remedies.

Need for Corrections

As published, the final regulation contained an error that may prove to be misleading and needs to be clarified.

On page 73 FR 76891 in § 407.9 item 22(a)(1) and § 457.8 item 27(e)(1)(i) the term "requirement of this title" is incorrect and should read "requirement of FCIC." Section 515(h) of the Act authorizes disqualification and the assessment of civil fine of persons who willfully and intentionally provide false or inaccurate information or fails to

comply with a requirement of FCIC. The term "requirement of this title" is confusing and provides no reference to a specific requirement.

List of Subjects in 7 CFR Parts 407 and 457

Administrative practice and procedures; Administrative remedies for non-compliance.

■ Accordingly, the 7 CFR part 407 and 457 is amended as follows:

■ 1. The authority citation for 7 CFR part 407 and 457 is revised to read as follows:

Authority: 7 U.S.C. 1506(l) and 1506(o).

PART 407—GROUP RISK PLAN OF INSURANCE REGULATIONS

■ 2. In § 407.9 amend item 22 by revising paragraph (a)(1) to read as follows:

§ 407.9 Group risk plan common policy.

* * * * *

22. Remedial Sanctions

* * * * *

(a) * * *

(1) The amount of the pecuniary gain obtained as a result of the false or inaccurate information provided or the noncompliance with a requirement of FCIC; or

* * * * *

PART 457—COMMON CROP INSURANCE REGULATIONS

■ 3. In § 457.8 amend item 27 by revising paragraph (e)(1)(i) to read as follows:

§ 457.8 The application and policy.

* * * * *

27. Concealment, Misrepresentation or Fraud.

* * * * *

(e) * * *

(1) * * *

(i) The amount of the pecuniary gain obtained as a result of the false or inaccurate information provided or the noncompliance with a requirement of FCIC; or

* * * * *

Signed in Washington, DC, on March 11, 2009.

William J. Murphy,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. E9-5793 Filed 3-18-09; 8:45 am]

BILLING CODE 3410-08-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2009-N-0665]

Implantation or Injectable Dosage Form New Animal Drugs; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for changing scientific nomenclature for a bovine pathogen on labeling for tylosin injectable solution.

DATES: This rule is effective March 19, 2009.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 12-965 for TYLAN (tylosin) Injection, an injectable solution used for the treatment of animal diseases associated with several bacterial pathogens. The supplemental NADA provides for changing a bovine pathogen name on product labeling. The supplemental NADA is approved as of February 24, 2009, and the regulations in 21 CFR 522.2640 and 522.2640a are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.