

Rulemaking to amend section 344.9(a)(3) to extend the time period for reporting quarterly personal securities transactions to 30-calendar days after the end of the calendar quarter.⁵ The comment period was 60 days, and expired on August 27, 2007. The FDIC received one comment on this proposal. The commenter supported the proposed amendment and agreed that the purpose of extending the reporting deadline was to align the FDIC's requirements with the SEC's, and to promote practical and uniform recordkeeping requirements.

III. Final Rule

As explained above, the FDIC received one industry comment on its proposal to extend the personal securities transactions reporting requirement to 30-calendar days after the end of the calendar quarter, which comment endorsed the FDIC's reasoning for its proposal. Accordingly, the FDIC is adopting the rule as proposed with no revisions.

IV. Regulatory Analysis and Procedure

A. Plain Language

Section 722 of the Gramm-Leach-Bliley Act (12 U.S.C. 4809) requires the FDIC to use "plain language" in all proposed and final rules published after January 1, 2000. The proposed rule requested comments on how the rule might be changed to reflect the requirements of GLBA. No comments were received.

B. Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act ("RFA") (5 U.S.C. 605(b)) the regulatory flexibility analysis otherwise required under section 603 of the RFA (5 U.S.C. 603) is not required if the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities and the agency publishes such certification and a statement explaining the factual basis for such a certification in the **Federal Register** along with its rule.

Pursuant to section 605(b) of the RFA, the FDIC certifies that this final rule will not have a significant impact on a substantial number of small entities. The FDIC does not expect that this rule will create any additional burden on small entities. In effect, the rule extends to 30-calendar days the reporting period within which officers and certain employees of state nonmember banks have to report their personal securities transactions and gives these individuals more latitude to report their quarterly securities transactions. Accordingly, a

regulatory flexibility analysis is not required.

C. Paperwork Reduction Act

The recordkeeping and reporting requirements for securities transactions in Part 344 constitute a collection of information as defined by the Paperwork Reduction Act. The information collection has been approved by the Office of Management and Budget under control number 3064-0028. The reporting requirements and burden associated with that collection would not be affected by this rule.

List of Subjects in 12 CFR Part 344

Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, title 12, chapter III, part 344, is amended as follows:

PART 344—RECORDKEEPING AND CONFIRMATION REQUIREMENTS FOR SECURITIES TRANSACTIONS

■ 1. The authority citation for Part 344 continues to read as follows:

Authority: 12 U.S.C. 1817, 1818, and 1819.

■ 2. In § 344.9, paragraph (a)(3) is revised to read as follows:

§ 344.9 Personal securities trading reporting by bank officers and employees.

(a) * * *

(3) In connection with their duties, obtain information concerning which securities are being purchased or sold or recommend such action, must report to the bank, within 30-calendar days after the end of the calendar quarter, all transactions in securities made by them or on their behalf, either at the bank or elsewhere in which they have a beneficial interest. The report shall identify the securities purchased or sold and indicate the dates of the transactions and whether the transactions were purchases or sales.

* * * * *

By Order of the Board of Directors.

Dated at Washington, DC, the 16th day of October, 2007.

Federal Deposit Insurance Corporation

Robert E. Feldman,

Executive Secretary.

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TENNESSEE VALLEY AUTHORITY

18 CFR Part 1301

Testimony by TVA Employees, Production of Official Records, and Disclosure of Official Information in Legal Proceedings

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Final rule.

SUMMARY: The Tennessee Valley Authority ("TVA") is publishing as a final rule a regulation governing access to TVA information and records in connection with legal proceedings in which neither the United States nor TVA is a party. This final rule establishes guidelines for use in determining whether TVA employees will provide testimony or records relating to their official duties. It also establishes procedures for requesters to follow when making demands on or requests to a TVA employee for official documents or to provide testimony. This final rule standardizes TVA's past practices, promotes uniformity in decisions, conserves the ability of TVA to conduct official business, preserves its employee resources, protects confidential information, provides guidance to requestors, minimizes involvement in matters unrelated to TVA's mission and programs, avoids wasteful allocation of agency resources, and avoids spending public time and money for private purpose.

DATES: The effective date of the regulation is October 25, 2007.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Goschy, Assistant General Counsel, Tennessee Valley Authority, 400 W. Summit Hill Drive, Knoxville, Tennessee 37902, (865) 632-8960.

SUPPLEMENTARY INFORMATION:

Background

TVA regularly receives subpoenas and other informal requests for documents and requests for TVA employees to provide testimony or evidence in cases in which TVA is not a party. Sometimes these subpoenas or requests are for TVA records that are not available to the public under the Freedom of Information Act. TVA also receives requests for TVA employees to appear as witnesses in litigation and to provide testimony relating to materials contained in TVA's official records or provide testimony or information acquired during the performance of the employees' official duties.

Although many other federal agencies currently have regulations in place to address these types of requests, and

⁵ 72 FR 35204 (June 27, 2007).

TVA itself has rules implementing the Freedom of Information Act that govern requests for information from the general public, TVA has not had official regulations governing subpoenas and other information requests for document production and testimony of TVA employees in legal proceedings. Issues about such requests that have arisen in recent years warrant adoption of regulations governing their submission, evaluation, and processing. Responding to these requests is not only burdensome, but may also result in a significant disruption of a TVA employee's work schedule and possibly involve TVA in issues unrelated to its responsibilities. In order to resolve these issues, many agencies have issued regulations, similar to this final regulation, governing the circumstances and manner in which an employee may respond to demands for testimony or for the production of documents.

Establishing uniform procedures for legal processes will ensure timely notice and promote centralized decision making. The United States Supreme Court upheld this type of regulation in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

On September 10, 2007, TVA published in the **Federal Register** its own proposed *Touhy* regulation, for codification in part 1301 of 18 CFR. See 72 FR 51572–51574, which provided for a 30 day comment period. TVA did not receive any comments on the proposed rule, and is issuing the final rule with no substantive changes from the proposed rule.

The final rule will formalize past practices already utilized by TVA in responding to requests for disclosure of official records or testimony by TVA employees when TVA is not a party to the litigation. Briefly summarized, the final rule will prohibit disclosure of official records or testimony by TVA's employees, as defined in section 1301.52, unless there is compliance with the rule. The final rule sets out the information that requesters must provide and the factors that TVA will consider in making determinations in response to requests for testimony or the production of documents. The final rule sets forth TVA's standard practice of providing employee testimony by affidavit only and clarifies those steps requesters must follow in order to obtain official TVA documents, including how to accomplish service of process on TVA. The final rule also establishes a new practice that service can now be accomplished by United States mail.

This final rule applies to a range of matters in any legal proceeding in

which TVA is not a named party. Current and former TVA employees will not provide testimony about specific matters involving information which they acquired during the performance of their official duties unless permitted to testify as provided in the rule. They are not restricted from providing testimony on their own time about general matters unconnected with the specific TVA matters.

This final rule will ensure a more efficient use of TVA's resources, minimize the possibility of involving TVA in issues unrelated to its responsibilities, promote uniformity in responding to such subpoenas and like requests, and maintain the impartiality of TVA in matters that are in dispute between other parties. It will also serve TVA's interest in protecting sensitive, confidential, and privileged information and records that are generated in fulfillment of TVA's statutory responsibilities.

The final rule is internal and procedural rather than substantive. It does not create a right to obtain official records or the official testimony of a TVA employee nor does it create any additional right or privilege not already available to TVA 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 TVA.

List of Subjects in 18 CFR Part 1301

Administrative practice and procedure.

■ For the reasons stated in the preamble, TVA amends 18 CFR Chapter XIII, as follows:

PART 1301—PROCEDURES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 16 U.S.C. 831–831ee, 5 U.S.C. 552.

■ 2. Part 1301 is amended by adding subpart D to read as follows:

Subpart D—Testimony by TVA Employees, Production of Official Records, and Disclosure of Official Information in Legal Proceedings

Sec.

- 1301.51 Purpose and scope.
- 1301.52 Definitions.
- 1301.53 General.
- 1301.54 Requirements for a demand for records or testimony.
- 1301.55 Responding to demands.
- 1301.56 Final determination.
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Subpart D—Testimony by TVA Employees, Production of Official Records, and Disclosure of Official Information in Legal Proceedings

§ 1301.51 Purpose and scope.

(a) *Purpose.* This part sets forth the procedures to be followed when TVA or a TVA employee is served with a demand to provide testimony and/or produce or disclose official information or records in a legal proceeding in which TVA or the United States is not a party, and where such appearance arises out of, or is related to, the individual's employment with TVA.

(b) *Scope.* This part applies when, in a judicial, administrative, legislative, or other legal proceeding, a TVA employee is served with a demand to provide testimony concerning information acquired in the course of performing official duties or because of official status and/or to produce official information and/or records.

§ 1301.52 Definitions.

The following definitions apply to this part:

(a) *Appearance* means testimony or production of documents or other material, including an affidavit, deposition, interrogatory, declaration, or other required written submission.

(b) *Demand* means a subpoena, order, or other demand of a court of competent jurisdiction, or other specific authority (e.g. an administrative or State legislative body), for the production, disclosure, or release of TVA records or information or for the appearance of TVA personnel as witnesses in their official capacities.

(c) *Employee* means any members of the Board of Directors, officials, officers, directors, employees or agents of TVA, except as TVA may otherwise determine in a particular case, and includes former TVA employees to the extent that the information sought was acquired in the performance of official duties for TVA.

(d) *General Counsel* means the General Counsel of TVA or a person to whom the General Counsel has delegated authority under this part.

(e) *Legal proceeding* means any and all pre-trial, trial, and post-trial stages of all judicial or administrative actions, hearings, investigations, or similar proceedings before courts, commissions, boards, or other judicial or quasi-judicial bodies or tribunals, whether criminal, civil, or administrative in nature.

(f) *Records or official records and information* means all information in the custody and control of TVA, relating to information in the custody and control of TVA, or acquired by a TVA

employee in performance of his or her official duties or because of his or her official status while the individual was employed by TVA.

(g) *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.

§ 1301.53 General.

(a) No employee shall appear, in response to a demand for official records or information, in any proceeding to which this part applies to provide testimony and/or produce records or other official information without prior authorization as set forth in this part.

(b) This part is intended only to provide procedures for responding to demands for testimony or production of records or other official information, and is not intended to, does not, and may not be relied upon to, create any right or benefit, substantive or procedural, enforceable by any party against TVA and the United States.

§ 1301.54 Requirements for a demand for records or testimony.

(a) *Service of demands.* Only TVA's General Counsel or his/her designee is authorized to receive and accept demands sought to be served upon TVA or its employees. All such documents should be delivered in person or by United States mail to the Office of the General Counsel, Tennessee Valley Authority, 400 W. Summit Hill Drive, Knoxville, Tennessee 37902.

(b) *Time limit for serving demands.* The demand must be served at least 30 days prior to the scheduled date of testimony or disclosure of records, in order to ensure that the General Counsel has adequate time to consider the demand and prepare a response, except in cases of routine requests for personnel and payroll records located on-site in Knoxville, where service 15 days prior will normally be considered sufficient. The General Counsel may, upon request and for good cause shown, waive the requirement of this paragraph.

(c) *Form of Demand.* A demand for testimony or production of records or other official information must comply with the following requirements:

(1) The demand must be in writing and submitted to the General Counsel.

(2) The demand must include the following information:

(i) The caption of the legal proceeding, docket number, and name and address of the court or other authority involved.

(ii) If production or records or other official information is sought, 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 records sought.

(iii) If testimony is sought, a description of the intended use of the testimony, a detailed description of how the testimony sought is relevant to the issues in the legal proceeding, and a specific description of the substance of the testimony sought.

(iv) 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 TVA to produce the documents or testimony.

(v) 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 a TVA employee, such as a retained expert.

(vi) The name, address, and telephone number of counsel to each party in the case.

(d) *Additional information.* TVA reserves the right to require additional information to complete the request where appropriate or to waive any of the requirements of this section at its sole discretion.

§ 1301.55 Responding to demands.

Generally, authorization to provide the requested material or testimony shall not be withheld unless their disclosure is prohibited by law or for other compelling reasons, provided the request is reasonable and in compliance with the requirements of this part, and subject to the following conditions:

(a) *Demands for testimony.* TVA's practice is to provide requested testimony of TVA employees by affidavit only. TVA will provide affidavit testimony in response to demands for such testimony, provided all requirements of this part are met and there is no compelling factor under paragraph (c) of this section that requires the testimony to be withheld. The General Counsel may waive this restriction when necessary.

(b) *Demands for production of records or official information.* TVA's practice is to provide requested records or official information, provided all requirements of this part are met and there is no compelling factor under paragraph (c) of this section that requires the records or official information to be withheld.

(c) *Factors to be considered in determining whether requested testimony or records or official information must be withheld.* The General Counsel shall consider the

following factors, among others, in deciding whether requested testimony or materials must be withheld:

(1) Whether production is appropriate in light of any relevant privilege;

(2) Whether production is appropriate under the applicable rules of discovery or the procedures governing the case or matter in which the demand arose;

(3) Whether the material requested is relevant to the matter at issue;

(4) Whether allowing such testimony or production of records would be necessary to prevent a miscarriage of justice;

(5) Whether disclosure would violate a statute, Executive Order, or regulation, including, but not limited to, the Privacy Act of 1974, as amended, 5 U.S.C. 552a;

(6) Whether disclosure would impede or interfere with an ongoing law enforcement investigation or proceeding, or compromise constitutional rights or national security interests;

(7) Whether disclosure would improperly reveal trade secrets or proprietary confidential information without the owner's consent;

(8) Whether disclosure would unduly interfere with the orderly conduct of TVA's functions;

(9) Whether the records or testimony can be obtained from other sources;

(10) Whether disclosure would result in TVA appearing to favor one litigant over another;

(11) Whether the demand or request is within the authority of the party making it; and

(12) Whether a substantial Government interest is implicated.

(d) *Restrictions on testimony or production of records or official information.* When necessary or appropriate, the General Counsel may impose restrictions or conditions on the production of testimony or records or official information. These restrictions may include, but are not limited to:

(1) Limiting the area of testimony;

(2) Requiring that the requester and other parties to the legal proceeding agree to keep the testimony under seal;

(3) Requiring that the testimony be used or made available only in the legal proceeding for which it was requested;

(4) Requiring that the parties to the legal proceeding obtain a protective order or execute a confidentiality agreement to limit access and any further disclosure of produced records or official information.

(e) *Fees for Production.* Fees will be charged for production of TVA records and information. The fees will be the same as those charged by TVA pursuant to its Freedom of Information Act regulations, 16 CFR 1301.10.

§ 1301.56 Final determination.

The General Counsel makes the final determination whether a demand for testimony or production of records or official testimony in a legal proceeding in which TVA is not a party shall be granted. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requesting party and, when necessary, the court or other authority of the final determination, the reasons for the grant or denial of the request, and any conditions that the General Counsel may impose on the production of testimony or records or official information.

§ 1301.57 Waiver.

The General Counsel may grant a waiver of any procedure described by this part where a waiver is considered necessary to promote a significant interest of TVA or the United States, or for other good cause.

Maureen H. Dunn,

General Counsel.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Paste

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 Luitpold Pharmaceuticals, Inc. The supplemental NADA provides for a revised human food safety warning for phenylbutazone paste, used in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective October 25, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, filed a

supplement to NADA 140-958 that provides for use of EQUIPHEN (phenylbutazone) Paste in horses for relief of inflammatory conditions associated with the musculoskeletal system. The supplemental NADA provides for a revised human food safety warning on product labeling. The supplemental NADA is approved as of September 26, 2007, and the regulations are amended in 21 CFR 520.1720c 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.

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

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

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1720c [Amended]

■ 2. In § 520.1720c, in paragraph (c)(3), remove "Not for use in horses intended for food." and add in its place "Do not use in horses intended for human consumption."

Dated: October 17, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

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BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Spinosad

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 new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for veterinary prescription use of spinosad chewable tablets to kill fleas and for the prevention and treatment of flea infestations on dogs for 1 month.

DATES: This rule is effective October 25, 2007.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA

141-277 that provides for veterinary prescription use of COMFORTIS (spinosad) Chewable Tablets to kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for 1 month. The NADA is approved as of September 25, 2007, and the regulations in 21 CFR part 520 are amended by adding § 520.2130 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,