FR 64954, October 31, 2000). On November 29, 2000, Bayer Corp. (Bayer), the sponsor of enrofloxacin (sold under the trade name Baytril® 3.23% Concentrate Antimicrobial Solution), requested a hearing on the proposed withdrawal. On February 20, 2002, the FDA's then Acting Principal Deputy Commissioner published a notice of hearing granting Bayer's request and identifying the factual issues that would be the subject of the evidentiary hearing (67 FR 7700, February 20, 2002). On March 21, 2002, the Animal Health Institute submitted a notice of participation under 21 CFR 12.45. Oral hearing for the purposes of cross-examination of witnesses was held at FDA from April 28 through May 7, 2003. On March 16, 2004, an FDA Administrative Law Judge (ALJ) issued an initial decision under 21 CFR 12.120. The ALJ determined that enrofloxacin had not been ''shown to be safe under the conditions of use upon the basis of which the application was approved,'' as required under section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(e)(1)(B)) and ordered that the approval of the NADA for Baytril be withdrawn. Bayer and CVM each filed exceptions to the initial decision on May 17, 2004.

In a notice published elsewhere in this issue of the **Federal Register**, FDA is announcing the final decision withdrawing approval of the NADA held by Bayer Corp., Agriculture Division, Animal Health, Shawnee Mission, KS 66201. NADA 140–828, Baytril® 3.23% Concentrate Antimicrobial Solution provides for use of enrofloxacin to treat poultry under § 520.813 (21 CFR 520.813). Relevant information concerning tolerances for residues of enrofloxacin in edible tissues of poultry is under § 556.228(a) (21 CFR 556.228(a)).

Therefore, in accordance with the final decision withdrawing approval and section 512(i) of the act (21 U.S.C. 360(b)(i)), FDA is amending the regulations to remove §§ 520.813 and 556.228(a).

The agency has determined under 21 CFR 25.33(g) 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

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 520 and 556 are 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.

§ 520.813 [Removed]

■ 2. Section 520.813 is removed.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.228 [Amended]

■ 4. Section 556.228 is amended by removing paragraph (a), by redesignating paragraph (b) as paragraph (a), and by adding and reserving new paragraph (b).

Dated: July 27, 2005.

Lester M. Crawford,

Commissioner of Food and Drugs.

[FR Doc. 05–15223 Filed 7–28–05; 2:31 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from North American Nutrition Companies, Inc., to Elanco Animal Health, A Division of Eli Lilly & Co.

DATES: This rule is effective August 1, 2005.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: North American Nutrition Companies, Inc., C.S. 5002, 6531 St., Rt. 503, Lewisburg, OH 45338, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 127–507 for TYLAN SULFA G Type A Medicated Article to Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285. Accordingly, the agency is amending the regulations in 21 CFR 558.630 to reflect the transfer of ownership.

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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.630 [Amended]

■ 2. Section 558.630 is amended in paragraph (b)(10) by removing ''017790'' and by adding in numerical sequence ''000986''.

Dated: July 11, 2005.

Steven D. Vaughn,

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

[FR Doc. 05–15161 Filed 7–29–05; 8:45 am]

BILLING CODE 4160–01–S

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2005–10]

Recordation of Documents

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of policy decision.

SUMMARY: This notice of policy decision clarifies three matters relating to practices concerning the recordation of documents pertaining to copyrights. First, it clarifies that a document will be indexed only under the titles appearing in the executed document. Second, it announces an interim practice on redaction of documents submitted for recordation, and states the intention of the Copyright Office to issue a notice of inquiry on the subject. Third, it provides notice that the Copyright Office is issuing a revised Document Cover Sheet.

DATES: Effective August 1, 2005.

FOR FURTHER INFORMATION CONTACT: Kent Dunlap, Principal Legal Advisor to the General Counsel. Telephone: (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION:

1. Background Information

Since 1870, the Copyright Office has recorded assignments and other documents relating to copyright. Although this function has been performed by the Office for over 100 years, the recordation process and the Office records concerning recordation are frequently misunderstood.

Generally, the original document to be recorded is submitted to the Office. Recordation makes the contents of a document part of the public records of the Copyright Office. The recorded document speaks for itself. The Office creates a public record of the document; that record is available (and searchable) in the Office's online catalog. A document is indexed under the names of the parties and the titles of works listed in the executed document.

When a document is recorded in the Copyright Office, that document is given a unique identifying number. The document is imaged and made available to the public for inspection and copying. The original document is returned to the sender with a certificate of recordation. The Office does not make determinations about the validity or effect of any document. Such determinations are within the purview of the courts.

2. Indexing of Titles

It has been a longstanding written practice of the Copyright Office to require that the index of recorded documents will only include titles contained in the recorded document, and that principle is embodied in section 205 of the copyright law. In administering the 1909 Copyright Act, Compendium of Copyright Office Practices I (1973) (Compendium I) made it clear that only titles that appeared in the document would be indexed and therefore appear in the records of the Office. Section 12.3.5. IV. provided as follows: ''Outside sources: A document will be indexed solely under the titles or other identifying matter it contains; no information or other information from sources outside the document will be supplied.''

This principle was retained in the 1976 Copyright Act, which provides that recordation of a document provides constructive notice of the facts stated in the recorded document, but only if ''the document, or material attached to it, *specifically identifies the work* to which it pertains so that, after the document is indexed by the Register of Copyrights, it would be revealed by a reasonable search under the title or registration number of the work.'' 17 U.S.C. 205(c) (emphasis added).

It is clear from the earliest discussions of this provision in the process of revision of the Copyright Act that the indexing by the Copyright Office, and the resulting constructive notice, would apply only to titles identified in the document or its attachments. The Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law, House Comm. on the Judiciary, 87th Cong., 1st Sess. House Committee Print (1961), contains the following statement concerning ''blanket transfers'':

> (2) Blanket transfers.—In some cases a recorded transfer will cover ''all the copyrights'' owned by the transferor with no identification of the individual works. It may be extremely difficult and time-consuming for a third person to ascertain whether the copyright in a particular work is covered by such a blanket transfer. We believe the statute should indicate that constructive notice is confined to the copyrights in works specifically identified by the recorded instrument.

Id. at 96. Thus, the Register's discussion clearly anticipated that the revised statute would not provide for constructive notice for works that are not specifically identified in the agreement or other document being recorded.

The provisions of the 1976 Act relating to documents, sections 204 and 205, were generally settled on in 1965. The 1965 Supplementary Report of the Register of Copyrights on the General Revision of the U.S. Copyright Law: 1965 Revision Bill, House Comm. on the Judiciary, 89th Cong., 1st Sess. at 230, House Committee Print (1965), explains the decision reflected in the statute with respect to requiring the specific titles to be included in a document for that document to be given constructive notice:

> Subsection (c) of section 205 implements another recommendation of the Report by providing that recordation of a document constitutes constructive notice of the facts it states only if ''the document, or material attached to it, specifically identifies the work to which it pertains so that, after the document is indexed by the Register of Copyrights, it would be revealed by a reasonable search under the title or registration number of the work; * * *.''

Id. at 77.

The phrase ''or material attached to it'' means an appendix or attachment that was formally part of the executed document. It is a common practice for copyright transactions to include important terms or information in schedules, appendices, or other attachments as part of the document. This interpretation is consistent with the phrase ''gives all persons constructive notice of the facts stated in the recorded document'' appearing in the first sentence of section 205(c). It is also consistent with the Office's practice under the 1909 Copyright Act, and the legislative history as reflected in the 1961 Report of the Register of Copyrights, and the 1965 Supplementary Report of the Register of Copyrights. Moreover, such a practice is consistent with the requirement in section 205(a) that a recorded document bear the signature of the person who executed it (or be accompanied by a sworn certification that it is a true copy of the original, signed document): the only reasonable reading of that requirement is that it does not permit recordation to extend constructive notice to information that was not part of the document at the time it was executed.

Several years after enactment of the revision of the 1976 copyright law, the Copyright Office issued Compendium of Copyright Office Practices II (1984) (Compendium II), which implemented procedures with respect to the new copyright law. Chapter 1600 concerned recordation of documents, and subsections 1607.02(c)–1607.04 provided as follows:

1607.02(c)

Blanket transfer. A blanket transfer, in which no individual titles are given, will be recorded without question. Example: ''Copyrights in all the published works of John Doe are hereby assigned. * * *''

1607.03

No titles given. When a document in which no titles are specified is recorded, the catalog entry will contain the notation: ''No Titles Given.''

1607.04

Outside sources. A document will be indexed solely under the titles or other

identifying matter it contains; no information from sources outside the document will be supplied. Thus, for example, the Copyright Office will not index titles given only in a covering letter.

In order to streamline processing, the office suspended Chapter 1600 of Compendium II regarding recordation of documents in 1992. 57 FR 27074 (1992). In 1998, it issued a new Compendium Chapter 1600. The treatment of blanket transfers in former subsections 1607.02(c)–1607.4 was simplified in new section 1608.03, which states: ''Outside sources. A document will be indexed only under the titles or other identifying matter it contains.'' This language actually returned to the language in Compendium I regarding practices under the 1909 Copyright Act. This reintroduction of the old language on ''outside sources'' into the new Compendium chapter meant no change in policy was intended.

However, the Office has discovered that an informal practice had evolved in the Documents Section which permitted a party submitting a document to attach a listing of titles to a document which, as executed, lacked titles, and to index titles that did not appear in the document if those titles were listed in a document cover sheet supplied by the Office. It is not clear when, how or why this practice commenced. It has been discontinued.

Copyright owners who wish to have titles of works appear in the index of recorded documents are cautioned to include a list of titles either in the body of the document or as an attachment made to the document before execution.

3. Redaction of Documents

On January 4, 1978, the Copyright Office issued interim regulations implementing recordation procedures. 43 FR 771 (1978). The Office regulations require that a document submitted for recordation must be ''complete on its face, and include any schedules, appendixes, or other attachments referred to in the document as being part of it.'' This provision has been included in the regulations since January 4, 1978. 43 FR 771 (1978).

In commenting on the interim regulation, the Authors League of America, Inc. requested that the requirement of completeness be clarified. 43 FR 35044 (1978). As a result, section 201.4(c)(2) was introduced into the regulation relating to the policies regarding attachments, and these clarifications remain as part of the regulations today. The commentary described these additions as ''our actual practices in the area.'' Id. at 35044. The current regulation reads as follows:

(2) To be recordable, the document must be complete by its own terms.

(i) A document that contains a reference to any schedule, appendix, exhibit, addendum, or other material as being attached to the document or made a part of it shall be recordable only if the attachment is also submitted for recordation with the document or if the reference is deleted by the parties to the document. If a document has been submitted for recordation and has been returned by the Copyright Office at the request of the sender for deletion of the reference to an attachment, the document will be recorded only if the deletion is signed or initialed by the persons who executed the document or by their authorized representatives. In exceptional cases a document containing a reference to an attachment will be recorded without the attached material and without deletion of the reference if the person seeking recordation submits a written request specifically asserting that: (A) The attachment is completely unavailable for recordation; and (B) the attachment is not essential to the identification of the subject matter of the document; and (C) it would be impossible or wholly impracticable to have the parties to the document sign or initial a deletion of the reference. In such exceptional cases, the Copyright Office records of the document will be annotated to show that recordation was made in response to a specific request under this paragraph.

(ii) If a document otherwise recordable under this title indicates on its face that it is a self-contained part of a larger instrument (for example: If it is designated ''Attachment A'' or ''Exhibit B''), the Copyright Office will raise the question of completeness, but will record the document if the person requesting recordation asserts that the document is sufficiently complete as it stands.

(iii) When the document submitted for recordation merely identifies or incorporates by reference another document, or certain terms of another document, the Copyright Office will raise no question of completeness, and will not require recordation of the other document. 37 CFR 201.4(c)(2). In addition to the stated practices on attachments, there has been a longstanding practice of allowing financial information (*e.g.*, a dollar amount) to be removed or blacked out. However, over the years larger redactions have been allowed. The Office generally has required that all pages be accounted for, meaning that if the text of an entire page was deleted, a blank page with the page number should be submitted at the appropriate place in the document with an indication that the entire page was redacted. This general policy, however, has been inconsistently applied.

The Copyright Office has concluded that the requirement of completeness as expressed in the regulation and the informal practice of permitting substantial redactions are inconsistent. If the Office is to continue its present practice of permitting substantial redactions, such as policy and the scope of the allowed redaction should be explicitly stated in the regulations. Moreover, opportunity for public comment on this important policy should be provided through a notice of inquiry. Before the Office issues such a notice of inquiry, further study is necessary to determine the origins, purpose and extent of the completeness doctrine as expressed in the regulation and the redaction practices. In the interim, the Copyright Office will permit redactions under following terms and conditions:

Interim Policy on Redaction of Documents. Documents containing blank or blocked-out sections, with the deletions initialed or labeled ''redacted,'' will be accepted for recordation if the document otherwise meets the recordation requirements and each page is accounted for, even if entire pages are redacted. Documents with missing pages will be returned as incomplete. The policies with respect to attachments as stated in 37 CFR 201.4(c)(2) will be applied, except that redactions will also be permitted in an attachment.

Notwithstanding this interim policy, persons submitting documents for recordation are cautioned that they would be well-advised to be conservative in the practice of redacting material from the submitted documents, limiting their omissions to small amounts of sensitive information, such as financial terms. It is possible that excessive redaction might deprive the document of the constructive notice provided under section 205. The Office notes that under section 205(c), constructive notice applies only to ''facts stated in the recorded document.'' A document which has been substantially redacted would necessarily limit constructive notice to that which appears in the document as recorded and could raise questions as to whether the Office's regulations were complied with—that is, whether the Office should have recorded the document with such redactions. The Office's interim policy should not be read as suggesting that it is appropriate to redact large portions from a document submitted for recordation, and it is possible that a court would refuse to recognize constructive notice for such a document, or in some way limit the constructive notice. After the Office has completed its inquiry into this issue, taking into account comments it receives from the public in the future, it is possible that the Office may decide to eliminate the possibility of redaction entirely, or to limit its application. It is therefore advised that if redaction is used at all, it be limited to a small amount of sensitive information, such as financial terms.

4. Revised Document Cover Sheet

In 1993, the Copyright Office made available an optional Document Cover Sheet in order to assist in recording documents. 58 FR 3297 (1993). It was anticipated that cataloging would be simplified because titles and parties

would be more readily accessible from the cover sheet than from the document itself. It was discovered, however, that often information was designated in the cover sheet which did not appear in the document. As a result, the Copyright Office had to limit indexing strictly to information appearing in the document, and copyright owners may have misinterpreted the purpose of the cover sheet as permitting the addition to the public record of information outside of the document by listing it in the cover sheet.

Despite the problems, the document cover sheet has been useful in a number of areas, particularly in providing a simple means to certify that a copy of a document bearing original signatures is a true and correct copy of the original document. For these reasons, the Copyright Office has issued a revised Document Cover Sheet retaining features which will assist in the processing of recording documents. While the revised Document Cover Sheet asks for identification of one party and one title for the purpose of connecting the Document Cover Sheet to the document, indexing will be based solely on the information appearing in the document. The Document Cover Sheet will remain optional, although its use is encouraged because it will assist in the recordation of submitted documents. Persons using the Document Cover Sheet should ensure that they use only copies dated 1/2005 or later, as indicated at the bottom of the page. Copies may be found on the Copyright Office Web site at *http://www.copyright.gov/forms/formdoc.pdf*. The Copyright Office continues to request that two copies of the Document Cover Sheet be submitted since one copy is used for imaging purposes, and the other copy is used to prepare the envelope for returning the document.

Dated: July 26, 2005.

Marybeth Peters,

Register of Copyrights.

[FR Doc. 05–15137 Filed 7–29–05; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[RME Docket Number R08–OAR–2004–CO–0005;FRL–7937–1]

Clean Air Act Approval and Promulgation of Air Quality Implementation Plan Revision for Colorado; Long-Term Strategy of State Implementation Plan for Class I Visibility Protection

AGENCY: Environmental Protection Agency (EPA)

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action approving a State Implementation Plan (SIP) revision submitted by the Governor of Colorado with a letter dated April 12, 2004. This revision replaces an August 19, 1998 submittal from the Governor and updates the Long-Term Strategy of the Visibility SIP to establish strategies, activities, and plans that constitute reasonable progress toward the National visibility goal. This action is being taken under section 110 of the Clean Air Act.

DATES: This rule is effective on September 30, 2005, without further notice, unless EPA receives adverse comment by August 31, 2005. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. R08–OAR–2004–CO–0005, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://docket.epa.gov/rmepub/index.jsp.* Regional Materials in EDOCKET (RME), EPA's electronic public docket and comment system for regional actions, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- E-mail: *long.richard@epa.gov* and *platt.amy@epa.gov.*
- Fax: (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 300, Denver, Colorado 80202–2466.
- Hand Delivery: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 999 18th Street, Suite 300, Denver, Colorado 80202–2466. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:55 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. R08–OAR–2004–CO–0005. EPA's policy is that all comments received will be included in the public docket without change and may be made available at *http://docket.epa.gov/rmepub/index.jsp*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do no submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA's Regional Materials in EDOCKET and Federal regulations.gov Web site are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk of CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET online or see the **Federal Register** of May 31, 2002 (67 FR 38102). For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the Regional Materials in EDOCKET index at *http://docket.epa.gov/rmepub/index.jsp.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on