Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Center for Food Safety and Applied Nutrition at 1–888–SAFEFOOD, Fax: 1–877–366–3322, or by e-mail: *industry@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 9, 2004 (69 FR 71562), FDA issued a final rule to implement section 306 of the Bioterrorism Act. The regulation requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. Persons subject to the regulation who employ 500 or more FTEs had to be in compliance by December 9, 2005, and those who employ 11–499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006 to be in compliance. ''Person'' includes an individual, partnership, corporation, and association.

On September 12, 2005, FDA issued the first edition of a guidance entitled ''Questions and Answers Regarding Establishment and Maintenance of Records.'' On November 22, 2005, FDA issued a second edition of that guidance and on June 6, 2006, FDA issued a third edition of that guidance. This document is the fourth edition of that guidance entitled ''Questions and Answers Regarding Establishment and Maintenance of Records (Edition 4)'' and responds to questions regarding persons covered by the regulation, and persons excluded by the regulation, including additional guidance on the farm exclusion. In addition, we are amending the response to question 4.2 to clarify that while post-harvesting activities related to hay are subject to the rule, certain activities that are part of harvesting remain within the farm exemption. This guidance is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart J. FDA is issuing this guidance as a Level 1 guidance. The guidance represents the agency's current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Consistent with FDA's good guidance practices regulation § 10.115(g)(2) (21 CFR 10.115), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, persons who employ 500 or more FTEs had to begin to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food by December 9, 2005, and those who employ 11–499 FTEs had to be in compliance by June 9, 2006. Persons who employ 10 or fewer FTEs have until December 11, 2006, to be in compliance. Clarifying the provisions of the final rule will facilitate prompt compliance with these requirements and complete the rule's implementation.

FDA continues to receive large numbers of questions regarding the records final rule, and is responding to these questions under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning establishment and maintenance of records in a single document that is periodically updated as the agency receives and responds to additional questions. The following four indicators will be employed to help users of this guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments and the guidance may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/~dms/recguid3.html*.

Dated: September 20, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8241 Filed 9–21–06; 1:22 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; Lasalocid

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 approval of a supplemental new animal drug application (NADA) filed by Purina Mills, Inc. The supplemental NADA provides for the use of a lasalocid Type A medicated article containing 20 percent lasalocid activity per pound to make free-choice Type C medicated feed mineral blocks used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

DATES: This rule is effective September 26, 2006.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *eric.dubbin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166–6812, filed a supplement to NADA 141–171 for use of BOVATEC 91 (lasalocid) Type A medicated article to make Purina Sugar Mag Block 1440 BVT Medicated Mineral Block, a free-choice Type C medicated feed used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The supplement provides for the use of a lasalocid Type A medicated article containing 20 percent lasalocid activity per pound. The supplemental NADA is approved as of August 18, 2006, and the regulations are amended in § 558.311 (21 CFR 558.311) to reflect the approval.

The basis of approval is discussed in the freedom of information summary.

In addition, FDA is amending § 558.311 to remove redundant text in an entry for combination use of single-ingredient lasalocid and chlortetracycline in cattle feed which was published in error in the **Federal Register** of April 27, 2006 (71 FR 24816). This correction is being made to improve the accuracy of the regulations.

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)(6) 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 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.

§ 558.311 [Amended]

■ 2. In § 558.311, in paragraph (b)(8), after the number ''15'' add the words ''and 20''; and in paragraph (e)(1)(xxvii) in the ''Indications for use'' column, remove ''control of control of'' and in its place add ''control of''.

Dated: September 15, 2006.

Steven D. Vaughn,

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

[FR Doc. 06–8261 Filed 9–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310, 1314

[Docket No. DEA–291I]

RIN 1117–AB05

Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: In March 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005, which establishes new requirements for retail sales of over-the-counter (nonprescription) products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The three chemicals can be used to manufacture methamphetamine illegally. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements. This action establishes daily and 30-day limits on the sales of scheduled listed chemical products to individuals and requires recordkeeping on most sales.

DATES: *Effective Dates:* September 21, 2006, except that §§ 1314.20, 1314.25, and 1314.30 (with the exception of § 1314.30(a)(2)) are effective September 30, 2006. Section 1314.30(a)(2) is effective November 27, 2006.

Comment Date: Written comments must be postmarked on or before November 27, 2006.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–291I'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). DEA is promulgating this rule as an interim final rule rather than a proposed rule because the changes being made codify statutory provisions, some of which are already in effect. Parts of the statute are self-implementing; certain changes related to retail sales became effective upon signature (March 9, 2006), others