of publicly available adjustment rates or through use of other reasonable methods at the discretion of the SSA Claims Officer.

(d) Replacement of lost or damaged property may be made in kind wherever appropriate at the discretion of the SSA Claims Officer.

(e) At the discretion of the SSA Claims Officer, you may be required to turn over an item alleged to have been damaged beyond economical repair to the United States, in which case no deduction for salvage value will be made in the calculation of actual value.

(f) Settlement of claims under the Act are final and conclusive.

§ 429.209 Are there any restrictions on attorney's fees?

No more than 10 percent of the amount in settlement of each individual claim submitted and settled under this subpart shall be paid or delivered to, or received by, any agent or attorney on account of services rendered in connection with that claim. A person violating this subsection shall be fined not more than $1,000.00 (31 U.S.C. 3721(i)).

§ 429.210 Do I have any appeal rights under this subpart?

(a) *Deciding Official.* While you may not appeal the decision of the SSA Claims Officer in regard to claims under the MPCECA, the SSA Claims Officer may, at his or her discretion, reconsider his or her determination of a claim.

(b) *Claimant.* You may request reconsideration from the SSA Claims Officer by sending a written request for reconsideration to the SSA Claims Officer within 30 days of the date of the original determination. You must clearly state the factual or legal basis upon which you base your request for a more favorable determination. Reconsideration will be granted only for reasons not available or not considered during the original decision.

(c) *Notification.* The SSA Claims Officer will send you a written determination on your request for reconsideration. If the SSA Claims Officer elects to reconsider your claim, the final determination on reconsideration is final and conclusive.

§ 429.211 Are there any penalties for filing false claims?

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be imprisoned for not more than 5 years (18 U.S.C. 287, 1001). In addition, that person may be liable for a civil penalty of not less than $5,000 and not more than $10,000 and damages of triple the loss or damage sustained by the United States, as well as the costs of a civil action brought to recover any penalty or damages (31 U.S.C. 3729).

[FR Doc. 04–18299 Filed 8–10–04; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0287]

21 CFR Parts 1, 5, 26, 203, 207, and 314

Change of Names and Addresses; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect name and address changes for the Office of Compliance, Center for Drug Evaluation and Research (CDER). This action is editorial in nature and is intended to provide accuracy and clarity to the agency's regulations.

EFFECTIVE DATE: August 11, 2004.

FOR FURTHER INFORMATION CONTACT: Mary C. Hennessey, Office of Compliance, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–8910.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 1, 5, 26, 203, 207, and 314 to reflect name and address changes for certain divisions of the Office of Compliance, CDER. The name changes are the result of a reorganization in CDER's Office of Compliance to improve coordination and communication and to enhance the office's capacity to implement risk management approaches to compliance activities. The address changes are due to the relocation of CDER's Office of Compliance.

Under this reorganization, the following organizational changes are reflected in the amendments made by this final rule:

- The name of the former Division of Labeling and Nonprescription Drug Compliance has been changed to the Division of New Drugs and Labeling Compliance,
- The name of the former Division of Prescription Drug Compliance and Surveillance has been changed to the Division of Compliance Risk Management and Surveillance, and
- Information sent to or obtained from the Drug Listing Branch is now maintained and distributed by CDER's Records Repository Team.

The amendments also include:

- The new mailing address of the Office of Compliance, CDER, and
- The new mailing addresses of specific divisions within the Office of Compliance (CDER) and for the Records Repository Team.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because these amendments are nonsubstantive.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 26

Animal drugs, Biologics, Drugs, Exports, Imports.

21 CFR Part 203

Labeling, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

21 CFR Part 207

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 5, 26, 203, 207, and 314 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.101 is amended by revising paragraph (d)(2)(ii) to read as follows:

§ 1.101 Notification and recordkeeping.

* * * * *

(d) * * *

(2) * * *

(ii) For human drug products—Division of New Drugs and Labeling Compliance (HFD–310), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

PART 5—ORGANIZATION

■ 3. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

§ 5.1100 [Amended]

■ 4. Section 5.1100 is amended under the heading ''CENTER FOR DRUG EVALUATION AND RESEARCH.[1]'' by removing the entries

''Office of Compliance.[6]

Division of Manufacturing and Product Quality.

Division of Prescription Drug Compliance and Surveillance.

Division of Labeling and Non-Prescription Drug Compliance.'' and by adding in its place the entries

''Office of Compliance.[1]

Division of New Drugs and Labeling Compliance (HFD–310).

Division of Manufacturing and Product Quality (HFD–320).

Division of Compliance Risk Management and Surveillance (HFD–330).''

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

■ 5. The authority citation for 21 CFR part 26 continues to read as follows:

Authority: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242l, 262, 264, 265.

■ 6. Appendix E to Subpart A of part 26 is amended under the heading ''B. For the United States:'' in the entry for ''Human Drugs'' by removing the phrase ''MPN I, 7520 Standish Pl., Rockville, MD 20855–2737, phone: 301–594–0054, fax: 301–594–2114'' and by adding in its place the phrase ''5600 Fishers Lane, Rockville, MD 20857, phone: 301–827–8910, fax: 301–827–8901''.

PART 203—PRESCRIPTION DRUG MARKETING

■ 7. The authority citation for 21 CFR part 203 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

§ 203.12 [Amended]

■ 8. Section 203.12 is amended in the first sentence by removing the phrase ''7520 Standish Pl., Rockville, MD 20855'' and by adding in its place the phrase ''5600 Fishers Lane, Rockville, MD 20857''.

■ 9. Section 203.37 is amended by revising the first sentence of paragraph (e) to read as follows:

§ 203.37 Investigation and notification requirements.

* * * * *

(e) *Whom to notify at FDA.* Notifications and reports concerning prescription human drugs shall be made to the Division of Compliance Risk Management and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. * * *

§ 203.70 [Amended]

■ 10. Section 203.70 is amended in paragraph (b)(1) by removing the phrase ''7500 Standish Pl., Rockville, MD 20855'' and by adding in its place the phrase ''5600 Fishers Lane, Rockville, MD 20857''.

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

■ 11. The authority citation for 21 CFR part 207 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

§ 207.7 [Amended]

■ 12. Section 207.7 is amended in paragraph (d) by removing the phrase ''Drug Listing Branch (HFD–334)'' and by adding in its place the phrase ''Records Repository Team (HFD–143)''.

§ 207.22 [Amended]

■ 13. Section 207.22 is amended in paragraph (a) by removing the phrase ''Drug Listing Branch (HFD–334)'' and by adding in its place the phrase ''Records Repository Team (HFD–143)''; and in paragraph (b) by removing the phrase ''Drug Listing Branch (HFD–334)'' and by adding in its place the phrase ''Records Repository Team (HFD–143)''.

■ 14. Section 207.37 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 207.37 Inspection of registrations and drug listings.

(a) A copy of the Form FDA–2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Records Repository Team (HFD–143), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, copies of these forms for establishments located within a particular geographic area are available for inspection at FDA district offices responsible for that geographical area. Copies of forms submitted by foreign drug establishments are available for inspection at the Division of Manufacturing and Product Quality, Foreign Inspection Team (HFD–325), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Upon request and receipt of a stamped, self-addressed envelope, the Records Repository Team, the Foreign Inspection Team, or the appropriate FDA district office will verify registration numbers or provide the location of a registered establishment. The mailing address for the Foreign Inspection Team is: Division of Manufacturing and Product Quality, Office of Compliance, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 15. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.81 [Amended]

■ 16. Section 314.81 is amended in paragraph (b)(3)(iii)(*b*) by removing the phrase ''Drug Listing Branch (HFD–334)'' and by adding in its place the phrase ''Records Repository Team (HFD–143)''.

§ 314.200 [Amended]

■ 17. Section 314.200 is amended in the second sentence of paragraph (a)(3) by removing the phrase ''Division of Drug Labeling Compliance (HFD–310)'' and by adding in its place the phrase ''Division of New Drugs and Labeling

Compliance (HFD–310), Office of Compliance''.

Dated: August 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18224 Filed 8–10–04; 8:45 am]

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; Oxytetracycline Hydrochloride Soluble Powder

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 abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The supplemental ANADA provides for a new packet size and strength of oxytetracycline hydrochloride soluble powder used to make medicated drinking water.

DATES: This rule is effective August 11, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200–066 that provides for use of AGRIMYCIN 166 (oxytetracycline hydrochloride) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a new packet size and strength of oxytetracycline hydrochloride soluble powder used to make medicated drinking water. The supplemental application is approved as of July 13, 2004, and the regulations are amended in 21 CFR 520.1660d to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

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.

List of Subject 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.

§ 520.1660d [Amended]

■ 2. Section 520.1660d is amended in paragraph (a)(6) by adding ''Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz).'' after the last sentence.

Dated: July 30, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–18361 Filed 8–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–216–FOR]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving, with certain exceptions, an amendment to the Kentucky regulatory program (the ''Kentucky program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky proposed revisions to the Kentucky Administrative Regulations (KAR) pertaining to water replacement, subsidence, bonding, definitions, hydrology, and permits. Kentucky revised its program to be consistent with the corresponding Federal regulations.

DATES: Effective August 11, 2004.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Telephone: (859) 260–8400. Internet address: *bkovacic@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act'; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. You can find background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and conditions of approval in the May 18, 1982, **Federal Register** (47 FR 21404). You can also find later actions concerning Kentucky's program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16 and 917.17.

II. Submission of the Proposed Amendment

By letter dated July 30, 1997 (administrative record no. KY–1410), Kentucky sent us, the Office of Surface Mining Reclamation and Enforcement (OSM), a proposed amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) The amendment revises 405 KAR at Sections 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160,