Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. To expedite the processing, written notices of participation may also be FAXED to 301–827–3079. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this notice.

Those persons interested in attending this meeting should submit their registration information, including name, title, firm name, address, telephone and fax number, to Toni Toomer (address below).

FOR FURTHER INFORMATION CONTACT: Toni Toomer, Center for Biologics Evaluation and Research (HFM–49), Division of Manufacturers Assistance and Training, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1310, FAX 301–827–3079.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 24, 1997, FDA published a final rule entitled, ''Changes to an Approved Application'' (62 FR 39890) and two notices of availability announcing corresponding guidance documents entitled, ''Guidance for Industry: Changes to an Approved Application: Biological Products'' (62 FR 39904) and ''Guidance for Industry: Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products'' (62 FR 39904).

FDA is announcing an open public meeting to discuss regulatory issues related to the final rule. The first part of the meeting will include an agency presentation of the regulatory provisions of the final rule and a discussion of the corresponding guidance documents, followed by a question and answer session.

In the second part of the meeting, the agency will solicit public comment on the use of a comparability protocol, which is an option available to applicants under the final rule. A comparability protocol describes the specific tests and validation studies and acceptable limits to be achieved to demonstrate the lack of adverse effect for specified types of changes on the safety or effectiveness of a product.

Every effort will be made to accommodate each person who wants to participate in the public meeting. However, because presentations will be limited to the second part of the meeting, the agency may not be able to accommodate all requests for formal presentations. Nevertheless, each person may participate in the open discussion at the end of the meeting. Accordingly, each person who wants to participate in the meeting is encouraged to submit a written request for participation, by close of business on September 3, 1997, and to include the following information: (1) File a written request for participation containing the name, address, telephone and fax number, affiliation, if any, of the participant, and topic of the presentation, and (2) submit a copy or a brief summary of their presentation, or any written comments for possible discussion at the meeting. The requested information, including the written notice for participation, may be submitted to the Dockets Management Branch (address above). Registration at the site will be done on a space-available basis on the day of the open public meeting beginning at 8:30 a.m.

Prior to the meeting, CBER will determine the schedule for the presenters. A schedule of the presenters will be filed with the Dockets Management Branch (address above) and mailed or faxed to each participant before the meeting. Interested persons attending the meeting who did not request an opportunity to make a presentation or those who did request an opportunity to make a presentation but due to the time limitations were not granted the request will be given the opportunity to make an oral presentation at the conclusion of the meeting, as time permits. There is no registration fee for this public meeting, but advance registration is suggested. Interested persons are encouraged to register early because space may be limited.

FDA will consider information presented and discussed at the meeting and written comments submitted to the Dockets Management Branch (address above) in the development of future guidance documents.

Dated: August 19, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22555 Filed 8-22-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate and Chlortetracycline; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of March 19, 1997 (62 FR 12951) that amended the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma Inc. The document stated incorrectly that bacitracin methylene disalicylate and chlortetracycline Type B feeds were included in the approval. This document corrects that error.

EFFECTIVE DATE: March 19, 1997.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

In FR Doc. 97–6876, appearing on page 12951, in the **Federal Register** of Wednesday, March 19, 1997, the following correction is made:

1. On page 12951, in the third column under the ''**SUMMARY**''caption, in line 9, ''Types B and C'' is corrected to read ''Type C''.

Dated: August 12, 1997.

Michael J. Blackwell,

Deputy Commissioner for Veterinary Medicine.

[FR Doc. 97–22553 Filed 8-22-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 86F–0060]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting without change the provisions of an interim rule regarding the approved use of selenium as a food additive in animal feeds. The interim rule implemented certain provisions of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act of 1994, and the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994.

EFFECTIVE DATE: September 9, 1997.

FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION:

I. Background

A. 1987 Amendments

In the **Federal Register** of April 6, 1987 (52 FR 10887), and corrected on June 4, 1987 (52 FR 21001), FDA issued a final rule amending the selenium food additive regulation (§ 573.920 (21 CFR 573.920)) to increase the maximum amount of selenium supplementation permitted in animal feeds. The action was based on a food additive petition (FAP 2201) filed by the American Feed Industry Association, Inc. (AFIA), 1701 North Fort Myer Dr., Arlington, VA 22209. In issuing the 1987 amendments FDA determined, based on an environmental impact analysis report submitted by AFIA, that the amended uses would not have a significant impact on the human environment.

B. 1993 Stay of 1987 Amendments

In the **Federal Register** of September 13, 1993 (58 FR 47962), FDA published a final rule that provided for a stay of the 1987 amendments to the selenium food additive regulations (hereinafter referred to as the 1993 final rule). This action resulted from allegations of inadequacies in FDA's finding of no significant impact and in the petitioners environmental assessment that supported the 1987 amendments. As a result of the stay of the 1987 amendments, the maximum permitted use levels of selenium in animal feeds returned to those levels permitted before FDA issued the 1987 amendments. FDA also stayed a 1989 amendment (54 FR 14214, April 10, 1989), to the regulation that provided for the use of a bolus for selenium supplementation at the increased levels, because the environmental assessment for the use of the bolus relied on the 1987 environmental analysis.

C. Legislative Actions

The 103d Congress passed two laws (Pub. L. 103–330 and Pub. L. 103–354) that provided for suspension of FDA's 1993 stay until certain conditions were met. As a result, selenium is allowed to be administered in animal feed as sodium selenite or sodium selenate in the complete feed for chickens, swine, turkeys, sheep, cattle, and ducks as provided for by the 1987 amendments to § 573.920, until further notice. The published regulation provides for the currently acceptable levels of selenium supplementation of feed; that is, levels not to exceed 0.3 part per million (ppm) in complete feeds of chickens, swine, turkeys, sheep, cattle, and ducks; in feed supplements for sheep not to exceed 0.7 milligram (mg) per head per day and in beef cattle not to exceed 3 mg per head per day; and in free-choice salt-mineral mixes for sheep up to 90 ppm but not to exceed 0.7 mg per head per day and for beef cattle up to 120 ppm in a mixture for free-choice feeding not to exceed an intake of 3 mg per head per day. In addition, the orally administered, osmotically controlled, and constant release bolus for beef and dairy cattle provided for on April 10, 1989 (54 FR 14214), was also available until further notice.

D. 1995 Interim Rule

In the **Federal Register** of October 17, 1995 (60 FR 53702), FDA published an interim rule that implemented the relevant provisions of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act of 1994, and the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. Under the provisions of the Administrative Procedure Act in 5 U.S.C. 553(b)(B) and FDA's administrative practices and procedures regulation in § 10.40(e) (21 CFR 10.40(e)), the Commissioner of Food and Drugs (the Commissioner) found for good cause that prior notice and comment on this interim rule was not necessary. The interim rule did not involve any exercise of discretion by the Commissioner. It merely repeated the terms of Pub. L. 103–354. As provided in FDA's administrative practices and procedures regulation at § 10.40(e), FDA provided an opportunity for public comment on whether the interim rule should be modified or revoked.

II. Summary of Comments

FDA received three comments in response to the interim rule. Two of the three comments were in full agreement with the interim rule. The third comment commented on the legislation rather than the interim rule. The comment indicated that no one opposed the stated purpose of the legislation, ''to permit higher levels of selenium addition to feeds to assure proper animal and poultry nutrition.'' This comment however objected to what it characterized as the statute's elimination of the quality assurance provision of the 1993 final rule that every batch of selenium premix be analyzed. Specifically, the comment stated that in cases where animals or poultry were killed by consuming feed over-fortified with selenium, overfortification of the premix was the cause. Therefore, the comment believed that adherence to good manufacturing practice alone does not result in appropriate control of selenium levels in animal feeds from an animal safety perspective and that the statute should have retained a premix batch analysis requirement. Because this comment addressed the statute rather than FDA's implementation of the statute in the interim rule, no changes have been made to this final rule.

III. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts and equity). The agency has reviewed this final rule and has determined that the rule is consistent with the principles set forth in the Executive Order and these two statutes. Furthermore, the final rule is not a significant regulatory action as defined by the Executive Order.

With this rule, FDA is adopting without change the provisions of an interim rule published in the **Federal Register** of October 17, 1995, regarding the approved use of selenium as a food additive in animal feeds. The interim rule implemented certain provisions of the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Act of 1994, and the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994. This legislation suspended the 1993 stay of a 1987 food additive approval, which amended the selenium food additive regulations to increase the maximum amount of selenium supplementation permitted in animal feeds, until certain conditions are met.

By now reaffirming the interim final rule, which merely implemented the legislation discussed in section I.D of this document, FDA has not imposed any new requirements on industry. The cost of the rule, therefore, is zero. The quality assurance provision stayed by the 1993 final rule, which required every batch of selenium premix to be analyzed, was not reinstated by the legislation or the interim final rule. The continued elimination of this requirement may result in a small cost savings to feed mills and others who were previously required to analyze every batch of premix and who will now have the option of doing so.

Under the Regulatory Flexibility Act, unless an agency certifies that a rule

will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency can identify at least one company which manufactures quality assurance products which are used in the selenium batch testing process. FDA has not prohibited the use of these batch testing products. They will still be available to feed mills if the feed mills wish to test every batch of selenium premix. As this final rule does not impose any new costs on this or other firms, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal Governments, in the aggregate, or by the private sector of $100 million. Because the rule does not require any expenditures by industry members or State or local governments, FDA is not required to perform a cost/benefit analysis under the Unfunded Mandates Reform Act.

IV. Final Action

The Commissioner has determined that the interim rule published on October 17, 1995, should be finalized without modification.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Accordingly, the interim rule amending 21 CFR 573.920 that was published in the **Federal Register** of October 17, 1995 (60 FR 53702), is adopted as a final rule without change.

Dated: August 8, 1997.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 97–22476 Filed 8-22-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 904

[SPATS No. AR–027–FOR]

Arkansas Regulatory Program

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

ACTION: Final rule; correction.

SUMMARY: OSM is correcting a final rule that appeared in the **Federal Register** of April 29, 1997 (62 FR 23129). This document amended the Arkansas regulatory program (hereinafter referred to as the ''Arkansas program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). When citing the part of the regulation that Arkansas proposed to remove, OSM inadvertently omitted the letter of the paragraph that was proposed for removal. Likewise, OSM inadvertently omitted the letter of the paragraph from the Federal regulation that was a counterpart to this State regulation that was proposed for removal.

EFFECTIVE DATE: The amendment to 30 CFR part 904 (62 FR 23129) is effective April 29, 1997.

FOR FURTHER INFORMATION CONTACT:

Michael C. Wolfrom, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 5100 East Skelly Drive, Suite 470, Tulsa, Oklahoma 74135–6548, Telephone: (918) 581–6430.

SUPPLEMENTARY INFORMATION: In FR Doc. 97–10990, appearing on page 23129 in the **Federal Register** of Tuesday, April 29, 1997, the following correction is made:

On page 23133, the second column, lines two and three, ''ASCMRC 816.89'' and ''30 CFR 816.89'' should read ''ASCMRC 816.89(d)'' and ''30 CFR 816.89(d)'', respectively.

Dated: August 7, 1997.

Charles E. Sandberg,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 97–22414 Filed 8–22–97; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–138–FOR; State Program Amendment No. 95–3 II]

Indiana Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Indiana regulatory program (hereinafter referred to as the ''Indiana program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to its rules pertaining to the small operator assistance program (SOAP). Topics covered in the proposed amendment are definitions for program administrator and qualified laboratory, eligibility for assistance, filing for assistance, application approval and notice, program services and data requirements, qualified laboratories, assistance funding, and applicant liability. The amendment is intended to revise the Indiana program to be consistent with the corresponding Federal regulations and to incorporate changes desired by the State.

EFFECTIVE DATE: August 25, 1997.

FOR FURTHER INFORMATION CONTACT:

Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521, Telephone (317) 226–6700.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program
II. Submission of the Proposed Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. Background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the July 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 914.10, 914.15, and 914.16.