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.