The data submissions for dishwashers have resulted in new ranges of comparability figures for these products, which will supersede the current ranges, published on September 16, 1996 (61 FR 48620).

The Commission also is amending the cost calculation formulas appearing in section 2 of appendices H and I to part 305. These sections contain heating and cooling performance cost information for central air conditioners and heat pumps. Manufacturers must provide the formulas on fact sheets and in directories so consumers can calculate their own costs of operation for the central air conditioners and heat pumps that they are considering purchasing. This amendment changes the figures in the formulas to reflect the current Representative Average Unit Cost of Electricity—8.31 cents per kilowatt-hour—that was published on November 18, 1996, by DOE (61 FR 58679) [4] and by the Commission on February 5, 1997 (62 FR 5316).

In consideration of the foregoing, the Commission revises appendix C, appendix H, and appendix I of part 305 by publishing the following ranges of comparability for use in required disclosures (including labeling) for dishwashers manufactured on or after November 24, 1997. The Commission also amends the cost calculation formulas in appendices H and I of part 305 so they will include the 1997 Representative Average Unit Cost for electricity. In addition, as of this effective date, manufacturers must base the disclosures of estimated annual operating cost required at the bottom of EnergyGuides for dishwashers on the 1997 Representative Average Unit Costs of Energy for electricity (8.31 cents per kilowatt-hour) and natural gas (61.2 cents per therm).

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to a Regulatory Flexibility Act analysis (5 U.S.C. 603–604) are not applicable to this proceeding because the amendments will not have a ''significant economic impact on a substantial number of small entities'' (5 U.S.C. 605). The Commission has determined that virtually none of the manufacturers of dishwashers fall within the definition of ''small entity'' as that term is defined in section 601 of the Regulatory Flexibility Act and in the regulations of the Small Business Administration, found in 13 CFR part 121. The Commission has concluded, therefore, that a regulatory flexibility analysis is not necessary, and certifies, under section 605 of the Regulatory Flexibility Act (5 U.S.C. 605(b)), that the amendments announced today will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for part 305 continues to read as follows:

Authority: 42 U.S.C. 6294.

2. Appendix C to part 305 is revised to read as follows:

Appendix C To Part 305—Dishwashers

Range Information

''Compact'' includes countertop dishwasher models with a capacity of fewer than eight (8) place settings.

''Standard'' includes portable or built-in dishwasher models with a capacity of eight (8) or more place settings.

Place settings shall be in accordance with appendix C to 10 CFR part 430, Subpart B. Load patterns shall conform to the operating normal for the model being tested.

Capacity	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Compact	302	302
Standard	344	699

3. In section 2 of Appendix H of Part 305, the text and formulas are amended by removing the figure ''8.6¢'' whenever it appears and by adding, in its place, the figure ''8.31¢''. In addition, the text and formulas are amended by removing the figure ''12.90¢'' whenever it appears and by adding, in its place, the figure ''12.47¢''.

4. In section 2 of Appendix I of Part 305, the text and formulas are amended by removing the figure ''8.6¢'' wherever it appears and by adding, in its place, the figure ''8.31¢''. In addition, the text and formulas are amended by removing the figure ''12.90¢'' wherever it appears and by adding, in its place, the figure ''12.47¢''.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–22489 Filed 8–22–97; 8:45 am]

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room air conditioners was published on November 13, 1995 (60 FR 56945). Because the Commission has never received any submissions of data for oil-fired instantaneous water heaters, the ranges for these products show ''no data submitted'' for all size categories. The Commission will not, therefore, amend the ranges for oil-fired instantaneous water heaters because they have not changed.

[4] This figure, along with national average cost figures for natural gas, propane, heating oil and kerosene, is published annually by DOE for the industry's use in calculating, among other figures, the cost figures required by the Commission's Rule.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314, 600, 601, 610, and 640

[Docket No. 95N–0329]

Biologics Regulations; Reporting Changes to an Approved Application; Open Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing an open public meeting to discuss issues related to the agency's final rule entitled, ''Changes to an Approved Application'' announced previously in the **Federal Register**. The final rule amended the biologics regulations for reporting changes to an approved application reviewed in the Center for Biologics Evaluation and Research (CBER) and the corresponding drug regulations for reporting changes to an approved application for specified biotechnology products reviewed in the Center for Drug Evaluation and Research (CDER). The purpose of the meeting is to present the regulatory procedures set forth in the final rule and to solicit public comment on a portion of the final rule that addresses the use of a ''comparability protocol.''

DATES: The open public meeting will be held on Wednesday, September 24, 1997, from 8:30 a.m. to 5 p.m. Registration for persons who want to participate at the meeting must be submitted to the agency by September 3, 1997, including written copies or a brief summary of the presentation, or any written comments for possible discussion at the meeting. Preregistration for persons who want to attend the meeting should be received by September 18, 1997.

ADDRESSES: The open public meeting will be held at the Quality Hotel, 8727 Colesville Rd., Silver Spring, MD 20910. Submit written requests for participation and written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23,

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.