and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns advertising, packaging, labeling and promotional practices related to the sale of optical drives that read information on compact disc read-only memory discs (''CD–ROM drives''). The Commission's complaint charges that respondent misrepresented that its CD–ROM drives were all or virtually all made in the United States when, in truth and in fact, its CD–ROM drives were assembled in the United States of primarily imported parts. In addition, the complaint charges that respondent misrepresented that CD–ROM drives that were made in China of primarily non-U.S. parts were all or virtually all made in the United States.

The proposed consent order contains a provision that is designed to remedy the charges and to prevent the respondent from engaging in similar acts and practices in the future. Part I of the proposed order prohibits the respondent from misrepresenting the extent to which any CD–ROM drive is made in the United States. The proposed order would allow respondent to represent that a CD–ROM drive is made in the United States so long as all, or virtually all, of the component parts of the CD–ROM drive are made in the United States and all, or virtually all, of the labor in manufacturing the CD–ROM drive is performed in the United States.

Part II of the proposed order requires the respondent to maintain materials relied upon in disseminating any representation covered by the order. Part III of the proposed order requires the respondent to distribute copies of the order to certain company officials and employees. Part IV of the proposed order requires the respondent to notify the Commission of any change in the corporation that may affect compliance obligations under the order. Part V of the proposed order requires the respondent to file one or more compliance reports. Part VI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed consent order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 99–1660 Filed 1–25–99; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0747]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Customer/Partner Satisfaction Surveys; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of December 24, 1998 (63 FR 71294). The document announced that a proposed collection of information had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The document was published with an incorrect docket number. This document corrects that error.

DATES: JANUARY 26, 1999.

FOR FURTHER INFORMATION CONTACT: Silvia R. Fasce, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–34111, appearing on page 71294 in the **Federal Register** of Thursday, December 24, 1998, the following correction is made:

1. On page 71294, in the first column, in the third line, ''[Docket No. 97N–0260]'' is corrected to read ''[Docket No. 98N–0747]''.

Dated: January 20, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1711 Filed 1–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pharmacy Compounding Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a meeting of the Pharmacy Compounding Advisory Committee which is scheduled for February 4 and 5, 1999. This meeting was announced in the **Federal Register** of January 6, 1999 (64 FR 886). The amendment is being made to reflect a change in the *Procedure* portion of the meeting notice. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Igor Cerny or Tony Slater, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8183 (301–443–0572 in the Washington, DC area), code 12440.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 6, 1999 (64 FR 886), FDA announced that a meeting of the Pharmacy Compounding Advisory Committee would be held on February 4 and 5, 1999. This amendment is being made to reschedule the time allotted for oral presentations from the public.

On page 887, in the first column, the *Procedure* portion of this meeting notice is amended to read as follows:

Procedure: Interested persons may present data, information or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 29, 1999. Oral presentations from the public will be scheduled on February 4, 1999, between approximately 11 a.m. and 12 m. for: Mild silver protein, 4-aminopyridine, and 3,4-diaminopyridine, and between approximately 3 p.m. and 4 p.m. for: Hydrazine; and on February 5, 1999, between approximately 10 a.m. and 11 a.m. for: Dinitrochlorobenzene, diphenylcyclopropenone, and squaric acid dibutyl ester, and between approximately 3 p.m. and 4 p.m. for: Pentylenetetrazole, cyclandelate, and betahistine dihydrochloride. Time allotted for each presentation may be

limited. Those desiring to make a formal oral presentation should notify the contact person before January 29, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 20, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–1709 Filed 1–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0759]

Determination of Regulatory Review Period for Purposes of Patent Extension; Anzemet®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Anzemet® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Anzemet® (dolasetron mesylate). Anzemet® is indicated for the prevention of nausea and vomiting associated with moderately-emetogenic cancer chemotherapy, including initial and repeat courses, and for the prevention of postoperative nausea and vomiting. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Anzemet® (U.S. Patent No. 4,906,755) from Hoechst Marion Roussel, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 10, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Anzemet® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Anzemet® is 2,443 days. Of this time, 1,729 days occurred during the testing phase of the regulatory review period, 714 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: January 5, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 5, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 29, 1995. The applicant claims September 28, 1995, as the date the new drug application (NDA) for Anzemet® (NDA 20–623) was initially submitted. However, FDA records indicate that NDA 20–623 was submitted on September 29, 1995.

3. *The date the application was approved*: September 11, 1997. FDA has verified the applicant's claim that NDA 20–623 was approved on September 11, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,578 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 29, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 26, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 18, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–1710 Filed 1–25–99; 8:45 am]

BILLING CODE 4160–01–F