FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5(a), section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 991–001) and the product license for the manufacture of Source Plasma issued to AM–Rho Laboratories, Inc., Jacksonville, FL 32216, were revoked effective July 3, 1996.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67(c).

Dated: December 19, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–186 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0080]

Determination of Regulatory Review Period for Purposes of Patent Extension; Olean

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Olean 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 food additive product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

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 food and color additives: (1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 or 721 of the Federal Food, Drug, and Cosmetic Act (the act) is initially submitted to FDA. An ''environmental effects'' test may be any test which: (a) Is reasonably related to the evaluation of the product's health effects, or both; (b) produces data necessary for marketing approval; and (c) is conducted over a period of not less than 6-months duration, excluding time required to analyze or evaluate test results. (2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 721 of the act is initially submitted to FDA and ends upon whichever of the following occurs last: (a) The regulation for the additive becomes final; or (b) objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or (c) proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted. 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 color or food additive will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(2)(B).

FDA recently approved for marketing the food additive product Olean (olestra). Olean is used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant, but not sweet) snacks. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Olean (U.S. Patent No. 4,005,196) from Proctor & Gamble Co. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 9, 1996, FDA advised the Patent and Trademark Office that this food additive product had undergone a regulatory review period and that the listing of Olean 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 Olean is 5,418 days. Of this time, 2,191 days occurred during the testing phase of the regulatory review period, while 3,227 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a major health or environmental effects test was begun:* April 2, 1981. The applicant does not specifically state a date when a test involving this food additive product was begun. However, FDA records indicate that the test was begun on April 2, 1981.

2. *The date a petition requesting the issuance of a regulation for use of the food additive under section 409 of the act was initially submitted:* April 1, 1987. FDA has verified the applicant's claim that the petition for Olean was initially submitted on April 1, 1987.

3. *The date the regulation for the food additive petition became effective:* January 30, 1996. The applicant claims that the regulation for the food additive became effective on January 24, 1996. However, FDA records indicate that, by its terms, the regulation for the food additive became effective on January 30, 1996 (61 FR 3118, January 30, 1996).

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 this application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 7, 1997, 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 7, 1997, 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: November 25, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–138 Filed 1–3–97; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Joint Meeting of the Nonprescription Drugs and Anti-Infective Drugs Advisory Committees

Date, time, and place. January 22, 1997, 8:30 a.m., Holiday Inn—Gaithersburg, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Anti-Infective Drugs Advisory Committee, code 12530. Please call the hotline for information concerning any possible changes.

General function of the committee. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Anti-Infective Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

Agenda—open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 13, 1997, 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 required to make their comments.

Open committee discussion. The joint committees will discuss issues relating to a health-care continuum model. In the Federal Register of June 17, 1994 (59 FR 31402 through 31452) the agency published a proposed rule for OTC health-care antiseptic drug products, i.e., patient preoperative skin preparations, surgical hand scrubs, and health-care personnel and antiseptic handwashes. In response to the proposed rule, the agency received a number of requests to consider a health-care continuum as a model for the regulation of OTC health-care antiseptic drug products. The proposed model defines six drug product categories (preoperative skin preparation, surgical hand scrub, health-care personnel handwash, food handler handwash, antimicrobial handwash, and antimicrobial body wash) and proposes testing requirements, key characteristics, and labeling for each of the categories. The model also proposes that the public health impact of these products is the lowest for consumer use products and continuously increases through the model as follows: Antimicrobial hand washes, antimicrobial body washes, food handler handwash, health-care personnel handwash, surgical hand scrub, and preoperative skin preparation. Conversely, the model proposes that the size of the population impacted by these products continuously decreases from consumer use products to professional use products. FDA is seeking an evaluation of the model's impact on public health in light of the isolation of pathogenic bacteria-bearing plasmids encoding for both topical antiseptic and multiple antibiotic resistance and is soliciting the advice and opinions from the advisory committees on this issue. The agency encourages investigators, academicians, and manufacturers of these products to respond to this notice with information bearing on this issue and to present their views on this issue before the committees.

A Joint Meeting of the Nonprescription Drugs Advisory Committee and the Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. January 23, 1997, 8:30 a.m., Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Tracy K. Riley or Joan C. Standaert, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.