Accounting Section (CO–5)
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, OH 45226

Centers for Disease Control and Prevention, CDC
and

Agency for Toxic Substances and Disease Registry (ATSDR)
Financial Management Office
1600 Clifton Road NE, (M/S D–04)
Atlanta, GA 30333

Health Care Financing Administration (HCFA)

Health Care Financing Administration, HCFA
Room C3–0927
7500 Security Boulevard
Baltimore, MD 21244

National Institutes of Health (NIH)

National Institutes of Health, NIH
Building 1, Room 222
Rocky Mountain Laboratory
Hilton, MT 59840

National Institutes of Health, NIH
National Institute of Mental Health
WAW Building, Room 562
St. Elizabeth's Hospital
Washington, DC 20032

National Institutes of Health, NIH
Frederick Cancer Research Facility
Fort Detrick Building, Room 427
Frederick, MD 21702–1201

National Institutes of Health, NIH
National Institutes of Environmental Health Sciences
Room B2–03, Building 101
Research Triangle Park, NC 27709

National Institutes for Health, NIH
National Institute on Drug Abuse
Addiction Research Center
Building C, Room 248
4940 Eastern Avenue
Baltimore, MD 21224

National Institutes for Health, NIH
Headquarters Office
Operations Accounting Branch
Building 31, Room B1–B63
9000 Rockville Pike
Bethesda, MD 20892–0134

Individual records of the following HHS Operating Divisions may be obtained from the Program Support Center (PSC):

Administration for Children and Families (ACF)

Administration on Aging (AoA)

Agency for Health Care Policy and Research (AHCPR)

Indian Health Service (IHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Office of the Secretary (OS)

Program Support Center (PSC)

Program Support Center, PSC
Division of Fiscal Services
5600 Fishers Lane
Room 16–05
Rockville, MD 20857

[FR Doc. 97–16 Filed 1–3–97; 8:45 am]

BILLING CODE 4150–04–P

Food and Drug Administration

[Docket No. 96N–0290]

AM–Rho Laboratories, Inc.; Revocation of U.S. License No. 991–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 991–001) and the product license issued to AM–Rho Laboratories, Inc., Jacksonville, FL, for the manufacture of Source Plasma. In a letter to FDA dated April 11, 1996, AM–Rho Laboratories, Inc., voluntarily requested revocation of its establishment and product licenses. In a letter dated July 3, 1996, FDA informed the firm that the establishment and product licenses for its Jacksonville location were revoked.

DATES: The revocation of the establishment license (U.S. License No. 991–001) and the product license became effective July 3, 1996.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 991–001) and product license for the manufacture of Source Plasma of AM–Rho Laboratories, Inc., 4130 Salisbury Rd., suite 2100, Jacksonville, FL 32216.

FDA inspected AM–Rho Laboratories, Inc., from October 16, 1995, through November 9, 1995. The inspection also involved a concurrent investigation that included interviews with individuals knowledgeable in the daily operations of the firm. The inspection of the facility and concurrent investigation revealed serious deviations from applicable Federal regulations. The deficiencies noted included, but were not limited to, the following: (1) Failure to properly immunize donors (21 CFR 640.66) by: (a) Permitting nonphysicians, working without a physician present, to inject at least 37 donors with red blood cell antigen; (b) immunizing at least one donor during plasmapheresis; and (c) permitting nonphysicians to select antigens and schedule immunizations; (2) failure to adequately determine donor suitability by: (a) Not excluding for the required 8-week period at least 21 donors who lost whole blood (21 CFR 640.63(e)); (b) routinely reevaluating donor hematocrit without recording the initial hematocrit values; and (c) routinely not complying with established standard operating procedures that required the cross checking of donors against deferral logs; (3) failure to maintain complete, accurate, and concurrent donor records (21 CFR 606.160) by: (a) Routinely forging physician's signatures on numerous records; (b) not completing maintenance and calibration records concurrently with work done; (c) inaccurate documentation of red blood cells not returned to the donor; (d) documenting as destroyed red blood cells that were returned to the donor; and (e) not providing a unit number for certain plasmapheresis products; (4) failure to maintain and follow standard operating procedures (21 CFR 606.100(b)) by: (a) Inadequately preparing phlebotomy sites on at least 25 donors; (b) not following the procedure for verifying correct reinfusion of red blood cells; and (c) permitting donors to leave the premises before the minimum time for postimmunization observation.

FDA concluded that the serious nature of the deficiencies identified during the inspection and during the concurrent investigation of AM–Rho Laboratories, Inc., were the direct consequence of the establishment's disregard for the applicable regulations and standards in the license application. FDA determined that these deficiencies constitute a danger to the public health that warranted suspension under 21 CFR 601.5(b) and 601.6(a). Additionally, the deficiencies noted demonstrated management's failure to exercise control over the facility relating to compliance and to assure adequate training and supervision of personnel as required by 21 CFR 600.10(a) and (b) and 606.20(a) and (b).

In a November 27, 1995, letter to the firm, FDA suspended the establishment license (U.S. License No. 991–001) and product license for Source Plasma. In a February 14, 1996, letter to FDA, the firm stated it would not seek reinstatement of the suspended license (U.S. License No. 991–001) and would destroy all plasma products in inventory. In a letter to FDA dated April 11, 1996, AM–Rho Laboratories, Inc., requested voluntary revocation of U.S. License No. 991–001.

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,