New Orleans and Nashville Districts, and Center for Food Safety and Applied Nutrition) is announcing a free public meeting as a followup to a meeting held in April 1995. The New Orleans and Nashville Offices of FDA will meet with interested persons in the States of Alabama, Louisiana, Mississippi, and Tennessee to address specific issues of concern to the seafood processing industry, other stakeholders, and FDA. Because the Interstate Shellfish Sanitation Conference addressed the issue of *Vibrio vulnificus* in raw oysters, this meeting will not cover that issue. Any other seafood issue will be open for discussion. The agency is holding this meeting to promote the President's initiative for a partnership approach between front-line regulators and the people affected by the work of regulatory agencies, and to create local partnerships.

DATES: The public meeting will be held on Friday, January 19, 1996, from 10 a.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Grand Casino Hotel Gulfport, 3305 West Beach Blvd., Gulfport, MS 39501, 601–870–7770 or 1–800–354–2450.

FOR FURTHER INFORMATION CONTACT: Sandra S. Baxter, FDA Nashville District, 297 Plus Park Blvd., Nashville, TN 37217, 615–781–5372, FAX 615–781–5383.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership Meetings would be held. This document announces a followup meeting to the one held on April 25, 1995, in Atlanta, GA. Those persons interested in attending this public meeting should FAX or send their registration, and comments or questions desired to be addressed to the meeting to the above contact person by January 5, 1996. There is no registration fee for this meeting. However, due to space limitations, early registration is required. The goal of this meeting is to listen to concerns and ideas of the regulated seafood industry and other stakeholders, and to identify possible next steps for the agency.

Dated: December 1, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–29767 Filed 12–6–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95E–0311]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for VALTREX® 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, rm. 1–23, 12420 Parklawn Dr., 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 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 VALTREX® (valacyclovir hydrochloride). VALTREX® is indicated for the treatment of herpes zoster (shingles) in immunocompetent adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for VALTREX® (U.S. Patent No. 4,957,924) from Burroughs Wellcome 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 October 5, 1995, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of VALTREX® 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 VALTREX® is 1,907 days. Of this time, 1,541 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: April 5, 1990. The applicant claims March 6, 1990, as the date the investigational new drug application (IND) became effective. The applicant claims that FDA waived the 30-day post-submission review period and the effective date of the IND relates back to the date of submission, March 6, 1990. According to FDA records, a safety meeting was held on March 23, 1990, for IND 34,526. The meeting is held within 30 days of receipt of an IND to determine its safety in humans. At the meeting it was agreed by the reviewing disciplines that the study was reasonably safe to proceed. There is no record of any waiver for this IND. If a waiver had been issued, there would have been no need to have the safety review meeting. Therefore, the correct IND effective date for IND 34,526 is April 5, 1990, 30 days after agency receipt of IND 34,526.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: June 23, 1994. FDA has