Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov.dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Trileptal (oxcarbazepine). Trileptal is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy, and as adjunctive therapy in the treatment of partial seizures in children ages 4 through 16 with epilepsy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Trileptal (U.S. Patent No. 4,559,174) from Novartis, 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 11, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Trileptal 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 Trileptal is 2,523 days. Of this time, 2,046 days occurred during the testing phase of the regulatory review period, while 477 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 (the act) (21 U.S.C. 355(i)) became effective*: February 18, 1993. The applicant claims February 4, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was February 18, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: September 25, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Trileptal (NDA 21–014) was initially submitted on September 25, 1998.

3. *The date the application was approved*: January 14, 2000. FDA has verified the applicant's claim that NDA 21–014 was approved on January 14, 2000.

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 1,690 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination, by November 23, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period, by March, 24, 2002. 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. Three copies of any information are to be submitted except that individuals may submit one copy. Comments are to be 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: September 5, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–23750 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Current Good Manufacturing Practice for Active Pharmaceutical Ingredients; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of workshops to discuss the application of the International Conference on Harmonisation (ICH) guidance for industry entitled ''Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients,'' which will be announced in a future issue of the **Federal Register**. The workshops, which will be held in collaboration with the Parenteral Drug Association, the Pharmaceutical Research and Manufacturers of America, and the Generic Pharmaceutical Association, are intended to provide a regulatory perspective on current good manufacturing practices (CGMPs) for active pharmaceutical ingredients (APIs). The workshops are being scheduled to help ensure that all APIs meet the standards for quality and purity they purport or are represented to possess.

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Erik N. Henrikson, Center for Drug

Evaluation and Research (HFD–320), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–827–0072, FAX 301–594–2202;

Leslie Zeck, Parenteral Drug Association, 7500 Old Georgetown Rd., suite 620, Bethesda, MD 20814, 301–986–0293, FAX 301–986–0296, e-mail: http://www.pda.org;

Alice E. Till, Pharmaceutical Research and Manufacturers of America, 1100 15th St. NW., Washington, DC 20005, 202–835–3400, FAX 202–835–3597, e-mail: http://www.phrma.org; or

Steve Bende, Generic Pharmaceutical Association, 1620 I St. NW., suite 800, Washington, DC 20006, 202–833–9070, FAX 202–833–9612, e-mail: http://www.genericaccess.com.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Should Attend?

This announcement is directed towards professionals involved in the manufacture, control, and regulation of APIs who will benefit from this training, including: Process/production engineers, quality assurance/quality control and regulatory affairs professionals, auditors, agents, brokers, traders, distributors, repackers and relabelers of APIs, consultants, regulatory investigators and GMP compliance officials, and reviewing chemists. Other entities or individuals may also be interested in attending.

B. Where and When Will These Workshops Be Held?

TABLE 1.—WORKSHOP LOCATIONS AND DATES

Workshop Address	Date and Local Time
Illinois: The Allerton Crowne Plaza, 701 North Michigan Ave., Chicago, IL	October 22 to 24, 2001, from 9 a.m. to 5 p.m.
New Jersey: Hyatt Regency Princeton, 102 Carnegie Center, Princeton, NJ	November 7 to 9, 2001, from 9 a.m. to 5 p.m.
California: The Sutton Place Hotel, 4500 MacArthur Blvd., Newport Beach, CA	February 25 to 27, 2002, from 9 a.m. to 5 p.m.
Puerto Rico: Caribe Hilton San Juan, Los Rosales St., San Geronimo Ground,San Juan, PR	April 8 to 10, 2002, from 9 a.m. to 5 p.m.

C. How Can I Participate?

You can participate in person. Anyone interested in the API workshops can register through any of the information contacts (addresses above).

D. Is There a Registration Fee for This Workshop?

Yes, a registration fee of $995 is required for this workshop. This registration fee includes workshop reference materials, lunch on each day, and a networking reception on day 1. Government employees qualify for a discounted rate of $395.

E. How Can I Get Additional Information, Including Copies of This Document or Other Related Documents?

Submit written requests for single copies of the Q7A guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your requests. Once the notice of availability is announced in a future issue of the **Federal Register**, those with electronic access will be able to obtain electronic copies of the guidance document on the Internet at three locations: http://www.fda.gov/cder/guidance/index.htm; http://www.emea.eu.int/pdfs/human/ich/410600en.pdf; or http://www.ifpma.org/ich5q.html#gmp. The notice of participation form, information about the workshops, and other related documents are available from any of the information contacts (addresses above) or from the Internet at http://www.fda.gov/cder/calendar.

II. Background Information

A. Why is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 3-day workshops to provide training of FDA personnel alongside industry participants on the ICH Q7A CGMP guidance for APIs. This is the first CGMP guidance developed jointly by regulators and industry and is intended for use worldwide. It affects manufacturers who manufacturer in, or intend to supply into, the ICH regions (United States, Europe, Japan).

B. What Will Be Covered?

FDA participation in these workshops will provide a regulatory perspective on the critical topic of the ICH guidance ''Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.'' Attendees will hear about the intent of the Expert Working Group that developed the Q7A guidance and learn how to interpret and apply the Q7A guidance, including special sections on APIs manufactured by cell culture/fermentation, and APIs for use in clinical trials.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23804 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 11, 2001, from 9 a.m. to 5 p.m.

Location: National Institutes of Health, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Contact: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, Woodmont II Bldg., 1451 Rockville Pike, Rockville, MD 20752, 419–259–6211, or John Treacy or Jayne E. Peterson , 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug applications (NDA) 20–665