ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (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–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 Director 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 BENICAR (olmesartan medocomil). BENICAR is indicated for the treatment of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for BENICAR (U.S. Patent No. 5,616,599) from Sankyo Company, Ltd., 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 30, 2002, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of BENICAR 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 BENICAR is 2,522 days. Of this time, 1,882 days occurred during the testing phase of the regulatory review period, while 640 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*: June 1, 1995. The applicant claims May 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 1, 1995, which was 30 days after FDA receipt of the IND.

2. T*he date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: July 25, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for BENICAR (NDA 21–286) was initially submitted on July 25, 2000.

3. *The date the application was approved*: April 25, 2002. FDA has verified the applicant's claim that NDA 21–286 was approved on April 25, 2002.

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 756 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 29, 2003. 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 January 27, 2004. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comment 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 14, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–19446 Filed 7–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0294]

Anesthetic and Life Support 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: Anesthetic and Life Support 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 September 9 and 10, 2003, from 8 a.m. to 5 p.m. Interested persons and organizations may submit written or electronic comments until October 10, 2003, to the Division of Dockets Management (*see* **ADDRESSES**).

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments.* Select ''2003N–0294—Opiate Risk Management'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm.

1093), Rockville, MD 20857, 301–827–7001, or e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 9, 2003, the committee will discuss Risk Management Plans for opiate analgesic drug products with particular attention to modified-release products. On September 10, 2003, the committee will discuss the abuse liability of and Risk Management Plans for Palladone, a modified-release hydromorphone drug product indicated for the treatment of moderate to severe pain in opioid tolerant patients.

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 September 2, 2003. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. on September 9, and between 11:30 a.m. and 12 noon on September 10, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 2, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Angie Whitacre at 301–827–7001 at least 7 days in advance of the meeting.

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

Dated: July 23, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–19506 Filed 7–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Additives and Ingredients Subcommittee of the Food 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: Additives and Ingredients Subcommittee of the Food 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 August 26 and 27, 2003, from 8:30 a.m. to 4:30 p.m., and August 28, 2003, from 8:30 a.m. to 12 noon.

Location: St. Regis Hotel (Crystal Ballroom), 923 16th St., NW, Washington, DC 20006, 202–638–2626.

Contact Person: Richard E. Bonnette, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3034, 202–418–3030, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: A small percentage of the population is allergic to natural rubber latex. FDA has received reports of sensitized people experiencing allergic reactions upon eating food they believed was prepared by food handlers wearing natural rubber latex gloves. The purpose of this meeting is to gather information and to provide advice and recommendations to the agency relating to reported allergic reactions to food prepared by workers wearing latex food service gloves.

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 August 20, 2003. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on August 27, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 20, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Richard E. Bonnette at least 7 days in advance of the meeting.

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

Dated: July 23, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–19448 Filed 7–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

Proposed Project: Ryan White Comprehensive AIDS Resources Emergency (CARE) Act: CARE Act Data Report (CADR) Form: (OMB No. 0915–0253)—Revision

The CARE Act Data Report (CADR) form, created in 1999 by the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA), is designed to collect information from grantees, as well as their subcontracted service providers, funded under Titles I, II, III and IV of the Ryan White (CARE) Act of 1990, as amended by the Ryan White CARE Act Amendments of 1996 and 2000 (codified under Title XXVI of