application (IND) became effective. However, FDA records indicate that the IND effective date was August 23, 1992, 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 of the act:* January 28, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Azopt™ (NDA 20–816) was initially submitted on January 28, 1997.

3. *The date the application was approved:* April 1, 1998. FDA has verified the applicant's claim that NDA 20–816 was approved on April 1, 1998.

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 579 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 27, 2000, 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 25, 2000, 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: December 23, 1999.

Jane A. Axelrad,

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

[FR Doc. 00–1875 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Quality of Life Subcommittee of the Oncologic 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: Quality of Life Subcommittee of the Oncologic 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 February 10, 2000, 8 a.m. to 4 p.m.

Location: Ramada Inn, Embassy Ballroom, 8400 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Quality of Life Subcommittee of the Oncologic Drugs Advisory Committee will discuss issues related to the study of quality of life for patients enrolled in cancer trials. Specific potential areas for discussion include definition of patient centered outcomes, clinical significance and interpretation of study results, and approaches to the statistical analysis of data.

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 February 3, 2000. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and between approximately 12:45 p.m. and 1:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2000, 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. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by February 3, 2000, to address issues specific to the topic before the committee.

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

Dated: January 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–1866 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5333]

Plans to Develop Guidance on Submitting an Archival Copy of an ANDA in Electronic Format; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Generic Drugs (OGD), within its Center for Drug Evaluation and Research, is announcing plans to develop guidance on submitting an archival copy of a complete abbreviated new drug application (ANDA) in electronic format. OGD has encouraged the electronic submission of some types of data on a voluntary basis since 1997. However, these submissions are not archivable and are made in addition to a complete paper submission. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record. OGD is soliciting comments from the public on its current program so it can consider these comments as it develops guidance for industry on the submission of complete, archivable ANDA's in electronic format. A draft guidance will be developed and made available for public comment. The ANDA electronic submission guidance will be one in a series of guidances the agency is developing to enable sponsors to submit archivable regulatory submissions in electronic format.

DATES: Submit written comments by March 27, 2000. General comments are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance describing OGD's current program entitled ''Preparing Data for Electronic Submission of ANDA's'' are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the 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 one self-addressed adhesive label to assist that office in processing your requests. Additional information can be found on the Internet at http://www.fda.gov/cder/OGD.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Cook, Center for Drug Evaluation and Research (HFA–358), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5683.

SUPPLEMENTARY INFORMATION: As part of the Prescription Drug User Fee Act, as amended by the Food and Drug Administration Modernization Act of 1997, the agency stated its plans to develop and update its information management capabilities to allow electronic submissions by 2002. In the **Federal Register** of January 28, 1999 (63 FR 4433 and 4432), the agency announced the availability of two guidances for industry entitled ''Providing Regulatory Submissions in Electronic Format—General Considerations'' and ''Providing Regulatory Submissions in Electronic Format—NDA's.'' These guidances are the first in a series of guidances for industry on submitting archivable regulatory submissions in electronic format. In the 1999 guidance on general considerations, the agency stated that guidance would be forthcoming on other submission types, including investigational new drug applications, ANDA's, and product licensing applications. As part of that effort, OGD is announcing plans to develop guidance on submitting an archival copy of an ANDA in electronic format. As soon as a draft guidance has been developed, it will be made available for public comment.

OGD has accepted submission of some types of electronic data in ANDA's since 1997. During 1998, OGD received 32 electronic submissions for bioequivalence data and 44 electronic submissions for chemistry, manufacturing, and control data representing 58 distinct ANDA's from 24 different companies. The OGD program has been voluntary with the paper submission serving as the archivable regulatory basis for review decisions. OGD plans to expand its electronic data submission program to include all parts of the ANDA, so that the archivable electronic submission can replace the paper submission as the ANDA of record.

Submission of an ANDA in electronic format is expected to yield many benefits to industry and FDA, including a more consistent submission, a more consistent and rapid review, and, in the future, reduction in archiving and storage space.

Electronic data files described in existing agency guidance and in more detail on the OGD program's Internet site will form the basis for paperless ANDA submissions. ANDA information not contained in the structured data submission (*e.g.,* narratives and graphics) will be submitted in Portable Document Format (PDF), consistent with agency policy recommendations about filing PDF text and other files explained in the 1999 general considerations guidance.

Pending completion of OGD's guidance on submitting archivable ANDA's in electronic format and in the absence of archiving capability, a complete paper ANDA submission is still required.

FDA is seeking input from interested parties on its current program for submitting electronic data to OGD. The agency would like to consider the public's comments as it develops guidance for industry on electronic submission of archivable ANDA's. A guidance for industry entitled ''Preparing Data for Electronic Submission of ANDA's'' describes OGD's current program.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the agency's current program and plans to develop guidance for industry on submitting complete, archivable ANDA's in electronic format. Two copies of any comments 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997), which provides for early public participation in the guidance development process.

Dated: January 11, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1869 Filed 1–26–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–841–853]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Revision of a currently approved collection;

Title of Information Collection: Durable Medical Equipment Regional Carrier, Certificate of Medical Necessity and Supporting Regulations in 42 CFR, Section 407.18 and 410.1;

Form No.: HCFA–841–853 (OMB# 0938–0679);

Use: A Certificate of Medical Necessity is a standardized format used to communicate information provided by an attending physician and a supplier of medical equipment and supplies. The information is used by carriers to determine the medical necessity of an item or service covered by the Medicare program and being used for the treatment of the Medicare beneficiary's condition. The CMNs being submitted for OMB review are necessary in order for HCFA to