360j(g)) for human tests to begin became effective February 1, 2001.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 28, 2002. FDA has verified the applicant's claim that the premarket approval application (PMA) for CYPHER (PMA P020023) was initially submitted June 28, 2002.

3. *The date the application was approved*: April 24, 2003. FDA has verified the applicant's claim that PMA P020023 was approved on April 24, 2003.

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 557 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 4, 2006. 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 August 2, 2006. 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. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 2006.

Jane A. Axelrad,

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

[FR Doc. E6–1436 Filed 1–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0017]

Human Subject Protection—Information for Institutional Review Boards, Clinical Investigators, and Sponsors; Rescission, Reissuance, and Development of Food and Drug Administration Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an initiative, the Information Sheet Guidance Initiative, to update its process for developing, issuing, and making available guidances intended for institutional review boards (IRBs), clinical investigators, and sponsors. Known as ''Information Sheets,'' these guidances have provided recommendations for IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to provide updated information and to issue the Information Sheets in accordance with FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop new Information Sheet Guidances as needed. The agency is also announcing the availability of five revised Information Sheet Guidances.

DATES: Submit written or electronic comments on the Information Sheet Guidance Initiative or the Information Sheet Guidances by April 4, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the Information Sheets are available on the Internet at *http://www.fda.gov/oc/gcp/guidance.html*. Submit written requests for single copies of the Information Sheet Guidances to the Office of Training and Communications (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: Bonnie M. Lee, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the Information Sheet Guidance Initiative, which will update the current process for developing, issuing, and making available Information Sheets intended for IRBs, clinical investigators, and sponsors.

Following issuance of human subject protection regulations by the Department of Health, Education, and Welfare and FDA in the late 1970s, IRBs frequently contacted FDA for advice on the best ways to achieve compliance with the new rules. In response, FDA issued informal guidance to answer the IRBs' specific questions. In 1984, FDA consolidated the informal guidance into a series of documents known as FDA's ''Information Sheets for Institutional Review Boards and Clinical Investigators.'' These Information Sheets were revised in 1995 and updated in 1998 to reflect new contact information. They were also edited to make them user friendly.

The Information Sheets have provided answers to frequently asked questions about human subject protection, informed consent, review of research, and related topics. The Information Sheets are intended to help IRBs, clinical investigators, and sponsors ensure that the rights and welfare of human research subjects are protected.

In 1997, the Food and Drug Administration Modernization Act required the agency to codify its GGPs policy. The GGP final rule, issued in 2000 (§ 10.115 (21 CFR 10.115)), requires that the agency make its guidance development and issuance procedures consistent and transparent. According to § 10.115, among other things, all FDA policy documents must be called guidance, and all agency guidance must be developed and issued according to the requirements in § 10.115. The Information Sheets are being converted to ''Information Sheet Guidance'' and are being issued in accordance with GGPs.

II. Process

The process of rescinding, revising, and reissuing all of the existing Information Sheets (there are approximately 40) may take several years to complete. The agency plans to make the process as transparent as possible. Therefore, FDA advises users to periodically check the agency's Information Sheet Web page at *http://www.fda.gov/oc/gcp/guidance.html*, throughout this time period. As guidances are revised and reissued and as new guidances are developed, they will be made available according to the GGP process and on this Web site.

III. Guidances Being Made Available With This Notice

The agency is announcing the availability of the following five Information Sheet Guidances that have been revised. These five Information Sheet Guidances replace the Information Sheets of the same titles (unless otherwise indicated) published in 1998.

- ''FDA Inspections of Clinical Investigators'' (previously entitled ''FDA Clinical Investigator Inspections''): This guidance is intended to provide information about FDA's inspections of clinical investigators conducted under FDA's Bioresearch Monitoring Program.
- ''FDA Institutional Review Board Inspections'': This guidance is intended to provide information about FDA's inspections of IRBs conducted under FDA's Bioresearch Monitoring Program.
- ''Waiver of IRB Requirements for Drug and Biologic Studies'' (previously entitled ''Waiver of IRB Requirements''): This guidance is intended to provide information about sponsor and sponsor-investigator requests for waivers of IRB requirements for drug and biologic studies.
- ''Significant Risk and Nonsignificant Risk Medical Device Studies'': This guidance is intended to provide advice to sponsors, clinical investigators, and IRBs on how to determine the differences between significant risk and nonsignificant risk medical device studies.
- ''Frequently Asked Questions About Medical Devices'' (previously entitled ''Medical Devices; Frequently Asked Questions about IRB Review of Medical Devices; Emergency Use of Unapproved Medical Devices''): This guidance is intended to assist sponsors, clinical investigators, and IRBs by answering common questions FDA receives concerning medical devices.

These Information Sheet Guidances are level 2 guidances according to FDA's GGPs regulation. FDA is implementing the guidances immediately without prior public comment because they contain only minor revisions to reflect current policy and/or are consistent with policy interpretations of the Department of Health and Human Service's Office for Human Research Protections. These Information Sheet Guidances represent the agency's current thinking on topics concerned with human subject protection. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to the Information Sheet Guidances or suggest topics for new Information Sheet Guidance. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these Information Sheet Guidances.

Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidances and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/oc/gcp/guidance.html*.

Dated: January 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1476 Filed 2–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0044]

Draft Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.'' The draft guidance was prepared by the Office of New Drugs and the Office of Medical Policy in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Center for Devices and Radiological Health (CDRH) at FDA. This document provides guidance to industry on the measurement of patient-reported outcomes (PROs) in studies to support medical product claims in approved labeling. The draft guidance describes how FDA evaluates PRO instruments used as effectiveness endpoints in clinical trials. It also describes our current thinking on how sponsors can develop and use PRO instruments to support claims in approved product labeling. By explicitly addressing the review issues identified in this guidance, sponsors can increase the efficiency of their endpoint discussions with FDA during the product development process, streamline FDA's review of PRO endpoint adequacy, and provide optimal information about the patient's perspective of treatment benefit at the time of product approval.

DATES: Submit written or electronic comments on the draft guidance by April 4, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance can also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Laurie B. Burke, Center for Drug Evaluation and Research (6411), Food and Drug Administration, 10903 New