

Use: Section 641 of the MMA mandated a demonstration that would pay for drugs/biologicals prescribed as replacements for existing covered Medicare drugs. A report to Congress evaluating the impact of this demonstration was also mandated. In order to enroll in this demonstration, a beneficiary will be required to submit the application forms. Beneficiaries who wish to be considered for a low-income subsidy must also provide the information on the "Application for Financial Assistance."

Form Number: CMS-10113

OMB#: 0938-0924.

Frequency: One per beneficiary.

Affected Public: Individuals or Households.

Number of Respondents: 50,000.

Total Annual Responses: 50,000.

Total Annual Hours: 20,417.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, Attention: Pam Gulliver, CMS-10113, Room C5-10-06, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 12, 2004.

John P. Burke, III,

*Paperwork Reduction Act Team Leader,
Office of Strategic Operations and Strategic
Affairs, Division of Regulations Development
and Issuances.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0204]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 20, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60 (OMB Control Number 0910-0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drugs, animal drugs, human, biological, medical device, food additive, or color additive products regulated by FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be

consumed during this review, which diminishes the value of the patent. In enacting 35 U.S.C. 156, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a document in the **Federal Register**, which describes the length of the regulatory review period, and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with "due diligence." The statute defines due diligence as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period." As provided in § 60.30(c), a due diligence petition "shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence." Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, seven requests for revision of the regulatory review period

have been submitted under § 60.24. Three regulatory review periods have been altered. Two due diligence petitions have been submitted to FDA under § 60.30. There have been no

requests for hearings under § 60.40 regarding the decisions on such petitions. In the **Federal Register** of May 19, 2004 (69 FR 28929), FDA published a

60-day notice requesting public comment on the information collection provisions. No comments were received. FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	7	1	7	100	700
60.30	2	0	2	50	100
60.40	0	0	0	0	0
Total					800

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0112]

Guidance for Industry on Independent Consultants for Biotechnology Clinical Trial Protocols; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols," dated August 2004. The guidance document provides guidance to sponsors of clinical trials for certain products on when and how to request from FDA the engagement of an independent consultant to participate in the review of protocols for clinical studies intended to serve as the primary basis of claims of efficacy. This guidance document finalizes the draft guidance of the same title dated May 2003.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; or the Division of Drug Information (HFD-240), Center for Drug Evaluation and

Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER voice information system at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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>.

FOR FURTHER INFORMATION CONTACT:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210; or Susan S. Johnson, Center for Drug Evaluation and Research, Office of New Drugs (HFD-20), 5515 Security Lane, suite 7215, Rockville, MD 20852, 301-594-3937.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols" dated August 2004. On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (PDUFA III). A letter from the Secretary of Health and Human Services (June 4, 2002), to Congress concerning PDUFA III included an addendum containing the performance goals and programs to which FDA committed as a means of facilitating the development and review of products subject to PDUFA III. One commitment was for FDA to establish a

program to allow sponsors of clinical trials for certain products to request that FDA engage an independent consultant to participate in the review of protocols for clinical studies that are intended to serve as the primary basis of claims of efficacy. This guidance document is intended to explain when and how a sponsor may take advantage of this program.

This guidance document finalizes the draft guidance document of the same title dated May 2003 (68 FR 24486, May 7, 2003). The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. 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 the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/ohrms/dockets/default.htm>, or <http://www.fda.gov/cder/guidance/index.htm>.