

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2007N-0240]

**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 November 13, 2007.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to [baguilar@omb.eop.gov](mailto:baguilar@omb.eop.gov). All comments should be identified with the OMB control number 0910-0233. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

**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 (21 U.S.C. 355(j)) and the Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, 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 the Drug Price Competition and Patent Term Restoration Act of 1984 and the Animal Drug and Patent Term Restoration Act of 1988, 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 notice that 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, nine requests for revision of the regulatory review period have been submitted under § 60.24. Four 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.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	9	1	9	100	900
60.30	2	0	2	50	100
60.40	0	0	0	0	0
Total					1,000

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

In the **Federal Register** of July 9, 2007 (72 FR 37242), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: October 4, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-20070 Filed 10-10-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0036]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Toll-Free Number for Consumer Reporting of Drug Product Side Effects: Comprehension

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Toll-Free Number for Consumer Reporting of Drug Product Side Effects: Comprehension" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

#### FOR FURTHER INFORMATION CONTACT:

Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 2, 2007 (72 FR 5056), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0603. The approval expires on January 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 4, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-20075 Filed 10-10-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Quality System Regulation Educational Forum on Design Controls; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Region, Dallas District Office, in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Quality System Regulation Educational Forum on Design Controls." This public workshop is intended to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

**Date and Time:** The public workshop will be held on April 4, 2008, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Omni Mandalay Hotel at Las Colinas, 221 East Las Colinas Blvd., Dallas (Irving), TX 75039. Directions to the facility are available at the FMDIC Web site at <http://www.fmdic.org/>.

**Contact Person:** David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, e-mail [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

**Registration:** FMDIC has a \$250 early registration fee. Early registration ends March 21, 2008. Registration is \$350 thereafter. To register online, please visit <http://www.fmdic.org/>. As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and e-mail, along with a check or money order for the appropriate amount payable to the FMDIC, to Dr. William Hyman, Texas A&M University, Department of Biomedical Engineering, 3120 TAMU, College Station, TX 75843-3120. Registration onsite will be accepted on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$350 payable to the FMDIC. The registration fee will be used to offset expenses of hosting the event, including meals, refreshments, meeting rooms, and materials.

If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 21 days in advance.

**Transcripts:** Transcripts of this event will not be available due to the format of this workshop. Event handouts may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. FMDIC and FDA present this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device QSR. The following topics will be discussed at the workshop: (1) Planning design controls, (2) design inputs and outputs, (3) design validation and verification, (4) design transfer and change, (5) control of suppliers, (6) design history file, and (7) how design controls relate to corrective and preventive action, change control, and risk management.

Dated: October 4, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-20077 Filed 10-10-07; 8:45 am]

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