

within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget,  
Paperwork Reduction Project. Fax: 202-395-7285. *E-mail:*

*OIRA\_SUBMISSION@OMB.EOP.GOV.*  
Attn: Desk Officer for the  
Administration for Children and  
Families.

Dated: December 22, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010-32592 Filed 12-27-10; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0198]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Notification" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, e-mail: [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 11, 2010 (75 FR 48696), 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 0910-0120. The approval expires on December 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: December 21, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-32508 Filed 12-27-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0447]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third Party Review Program Under the Food and Drug Administration Modernization Act

**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 (the PRA).

**DATES:** Fax written comments on the collection of information by January 27, 2011.

**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: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0375. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, e-mail: [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**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.

### Medical Devices; Third Party Review Program Under the Food and Drug Administration Modernization Act—(OMB Control Number 0910-0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) of the FD&C Act (21 U.S.C. 360) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

#### I. Reporting

##### *510(k) Reviews Conducted by Accredited Third Parties*

According to FDA's data in 2009, the Agency has experienced that the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

#### II. Recordkeeping

Third party reviewers are required to keep records of their review of each submission. According to FDA's in 2009, the Agency anticipates approximately 260 submissions of 510(k)s for third-party review per year.

In the **Federal Register** of September 22, 2010 (75 FR 57801), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it was not PRA related.

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

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

Section 523 of the FD&C Act	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Requests for accreditation .....	1	1	1	24	24
510(k) reviews conducted by accredited third parties .....	10	26	260	40	10,400
Total .....					10,424

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Section 523 of the FD&C Act	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
510(k) reviews .....	10	26	260	10	2,600

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

Dated: December 21, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-32603 Filed 12-27-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-P-0326]

#### Determination That TRANDATE (Labetalol Hydrochloride) Tablets, 300 Milligrams and 400 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that TRANDATE (labetalol hydrochloride) tablets, 300 milligrams (mg) and 400 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as the ANDAs meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Deborah Livornese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993-0002, 301-796-0719.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term

Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug. Under § 314.161(a)(2), FDA must determine whether a listed drug was withdrawn from sale for reasons of

safety or effectiveness whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, are the subject of NDA 18-716, held by Prometheus Laboratories, Inc., and initially approved on August 1, 1984. TRANDATE is indicated for the management of hypertension. TRANDATE (labetalol hydrochloride) tablets, 300 mg and 400 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. TRANDATE (labetalol hydrochloride) tablets, 400 mg, have never been marketed. In previous instances (*see, e.g.*, 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

JRRapoza Associates, Inc., submitted a citizen petition dated June 16, 2010 (Docket No. FDA-2010-P-0326), under 21 CFR 10.30, requesting that the Agency determine whether TRANDATE (labetalol hydrochloride) tablets, 300 mg, were withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 400 mg strength, on our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that