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.


Robert Sargis, Reports Clearance Officer.

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

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 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 Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 22, 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 0910–0375. Also included in the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:
Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: Daniel.Gittleson@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—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.
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 this 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 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 15–716, 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 23497, 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...