To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on April 3, 2007.

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 26, 2007.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E7–1686 Filed 2–1–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0036]

Agency Emergency Processing Under Office of Management and Budget Review; Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Labeling Comprehension Study

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns an experimental study to test labeling statement alternatives for certain prescription and over-the-counter (OTC) drug product labeling.

DATES: Fax written comments on the collection of information by March 5, 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. This information is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320) and is essential to the agency's mission to protect the public health and safety. Section 17 of the Best Pharmaceuticals for Children Act (the BPCA) (Public Law 107–109) requires FDA to issue a final rule mandating the addition of a statement to the labeling of each drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355). Under the BPCA, the labeling statement is required to include: (1) A toll-free number for consumers to use to report drug product side effects and (2) a statement that the number is to be used only for reporting side effects and is not intended to seek or obtain medical advice (the side effects statement). The use of normal clearance procedures would further delay FDA's issuance of a final rule to comply with this congressional mandate.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products; Labeling Comprehension Study

On April 22, 2004 (69 FR 21778), FDA published a proposed rule with a proposed side effects statement for certain prescription drug product labeling and a proposed side effects statement for certain OTC drug product labeling. In the proposed rule, FDA solicited comments on the wording of these side effects statements. We received 12 comments suggesting changes to the specific wording of the proposed side effects statements. We also received several comments suggesting that FDA engage in research to study consumer comprehension of the wording of the proposed side effects statements. Among the reasons cited for testing the statements were: (1) To determine the best and most precise wording for the statements, (2) to evaluate consumer comprehension of the proposed statements, and (3) to address concerns that consumers who read the statement will mistakenly call FDA in search of medical advice. In addition, during the clearance process for the proposed rule, both the Office of Information and Regulatory Affairs of OMB and the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services suggested that FDA conduct consumer studies on the wording of the side effects statements. After the publication of the proposed rule and based on the comments received, FDA decided to conduct research to study the wording of the proposed side effects statements before issuing a final rule.

FDA conducted two focus groups (OMB Control No. 0910–0497) to narrow the field of potential statement alternatives. Based on the findings from the focus groups, FDA has selected several statements for quantitative testing in an experimental study of consumer comprehension. The experimental study will test several ways of stating the required information for maximum comprehension of factual information and necessary action. The experimental study will provide quantitative data to inform FDA's selection of the side effects statements to fulfill the requirements of the BPCA. Each participant will be exposed to only one side effects statement, in a ''between-subjects'' or ''monadic'' design. Participants initially will see one statement in the context of either a prescription drug bottle or an OTC Drug Facts label, depending on which condition they are in, and will all answer the same series of questions. For the remainder of the study, each participant will see the statement as they answer questions specifically about the statement. The experimental study data will be collected via the Internet from members of a consumer panel maintained by an external research organization. Panel members are recruited by a variety of means designed to reflect all segments of the population. They are required to have a computer with Internet access. Studies begin with an e-mailed invitation to the sampled

respondents. Each panel member has provided demographic data for their household that allows for the selection of samples that resemble closely the distribution of the U.S. population on age, gender, education, and race/ethnicity. A participant recruitment questionnaire (screener) will be used to ensure recruitment criteria are met. Conventional statistical techniques for experimental data (such as descriptive statistics, analysis of variance, and regression models) will be used to analyze the data. This proposed data collection will be one-time only. No successive related data collections are planned. Testing the statements experimentally will provide valuable information on the comprehension, usefulness, and selection of the side effect statements to be included in the final rule.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Administration of Participant Screener	1,684	1	1,684	0.01	17
Administration of Participant Questionnaire	1,600	1	1,600	0.15	240
Total					257

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

Dated: January 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1674 Filed 2–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0430]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 456h and 2567

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 March 5, 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.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 456h and 2567—(OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 506B of the act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the agency to make publicly available information that pertains to the status of these studies.

Under section 506B(a) of the act, applicants that have committed to conducting a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

Section 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60, 610.61, and 610.62 (21 CFR part 610). The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document. Section 601.5(a) requires a licensee to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the licensee to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly review all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5)