DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0648]

Agency Information Collection Activities; Proposed Collection; Comment Request; PDUFA Pilot Project Proprietary Name Review

AGENCY: Food and Drug Administration, HHS

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the evaluation of proposed propriety names by pharmaceutical firms and the submission of the data generated from those evaluations to FDA for review under a pilot program. FDA plans to begin enrollment in the pilot program by the end of fiscal year (FY) 2009.

DATES: Submit written or electronic comments on the collection of information by February 23, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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 Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with the pilot program, FDA invites comments on the following 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.

PDUFA Pilot Project Proprietary Name Review

In the **Federal Register** of October 7, 2008 (73 FR 58604), FDA announced the availability of a concept paper entitled ''PDUFA Pilot Project Proprietary Name Review.'' The concept paper describes how pharmaceutical firms may evaluate proposed proprietary names and submit the data generated from those evaluations to FDA for review under a pilot program to begin by the end of FY 2009.

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85, 121 Stat. 823), which includes the reauthorization and expansion of the Prescription Drug User Fee Act (PDUFA IV). As part of the reauthorization of PDUFA IV, FDA committed to certain performance goals, including the goal of using user fees to implement various measures to reduce, among other things, medication errors related to look-alike and sound-alike product proprietary names. FDA also agreed to develop and implement a voluntary pilot program to enable pharmaceutical firms participating in the pilot to evaluate proposed proprietary names and to submit the data generated from those evaluations to FDA for review. The concept paper is intended to help pharmaceutical firms choose appropriate proprietary names for their drug and biological products before submitting marketing applications to FDA and describes how pharmaceutical firms may use ''best practices'' to carry out their own proprietary name reviews and provide FDA with the data that result from those reviews. The goals of the concept paper and the voluntary pilot program are to minimize the use of names that are misleading or that are likely to lead to medication errors, to make FDA's marketing application review more efficient, and to make regulatory decisions more transparent. The concept paper explains how an applicant who chooses to participate in the pilot program could assess a proposed proprietary name for safety (i.e., potential for medication errors) and, at the applicant's option, for promotional implications, before marketing application approval and subsequent marketing of a drug or biological product in the United States, and how to submit the results of the assessment for review under the pilot program.

As required by the PRA, this document is the first of two **Federal Register** notices that FDA must publish to provide an opportunity for public comment on the information collection that will result from the pilot program. The information described in the concept paper and the data collected may not be submitted to FDA until OMB has approved the information collection associated with the pilot program. After OMB approval, FDA will accept requests to register for the pilot program. FDA will announce OMB's approval and other details on participating in the pilot program in the **Federal Register**. FDA expects that the pilot program will begin by the end of FY 2009.

The information collection that will result from the voluntary pilot program, as described in the concept paper, consists of the following:

- Applicants should contact FDA to register and indicate the approximate date of their proprietary name submission, as described in the concept paper and as will be described in more detail when FDA announces OMB's approval and the specific information on participating in the pilot program.
- Applicants should contact the appropriate FDA Center 120 days prior to the intended date of the proposed proprietary name submission to discuss the specific details of the planned submission. Applicants should communicate with the Director in the Division of Medication Error Prevention and Analysis in the Office of

Surveillance and Epidemiology in the Center for Drug Evaluation and Research, or the Branch Chief at the Advertising and Promotion Labeling Branch of the Division of Case Management in the Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research, concerning any questions about their proposed submissions. For prescription products, applicants should inform the appropriate center at the 120-day pre-submission discussion if they plan to use alternative or additional methods to evaluate the safety of their proposed proprietary name. For nonprescription products, sponsors should discuss with FDA different protocols that could be used for their specific drug products prior to the submission of the proprietary name.

- Applicants should submit two separate sets of product name-related information to enable parallel reviews by FDA as follows: (1) A comprehensive evaluation of the proposed proprietary name including the information and data listed in Appendix B (''Proposed Template For A Pilot Program Submission'') of the concept paper; and (2) the proprietary name information that they would ordinarily submit under FDA's current practice. (Note: The proprietary name information ordinarily submitted under FDA's current practice is not included in the estimates in table 1 of this document because this information collection is already approved under OMB Control Numbers 0910–0001 and 0910–0338).
- After review of the proprietary name submissions, and if FDA informs the applicant that the proposed first-choice proprietary name is unacceptable, the applicant should confirm in writing that it would like its originally submitted second-choice name reviewed, or the applicant should submit an alternative second-choice name along with the information described in the concept paper. At that time, FDA will begin review of the second-choice name. If an applicant has submitted a complete proprietary name analysis for the second-choice name, the responsible center will use discretion to determine whether to review the applicant's analysis in addition to conducting its own analysis using the traditional approach. Although FDA would ideally review the applicant's completed proprietary name analysis for the second-choice name, factors such as staffing and timelines will be used in making this determination.

FDA estimates the burden of this collection of information in table 1 of this document. The ''hours per response'' is for all of the submissions and notifications to FDA described under the bulleted paragraphs above and is based on information provided by industry as well as FDA's familiarity with the time required for this information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pilot Project Proprietary Name Review	20	1	20	480	9,600

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0375] (formerly Docket No. 2004D–0555)

Guidance for Industry and Food and Drug Administration Staff; ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300.'' This guidance document describes a means by which male condoms made of natural rubber latex (latex condoms) may comply with the requirement of special controls for class II devices. FDA believes that the labeling recommendations contained in this guidance, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of latex condoms without spermicidal lubricant. In the **Federal Register** of November 10, 2008 (73 FR 66522), FDA published a final rule that amended the classification regulation for condoms from class II (performance standards) to class II (special controls) and designated this guidance document as the special control for male condoms made of natural rubber latex classified under that regulation.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for