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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 00N-1604]

Agency Information Collection Activities; Proposed Collection; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for over-the-counter (OTC) test sample collection systems for drugs of abuse testing.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All documents should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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 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** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (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.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified OTC test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results.

The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

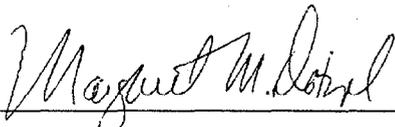
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
809.10	20	1	20	100	2,000

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

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: November 9, 2000



Maraget M. Dotzel
Associate Commissioner for Policy

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