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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-2553]

**Agency Information Collection Activities: Proposed Collection; Comment Request; Citizen Petition**

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

**ACTION:** Notice.

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**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 reporting requirements contained in existing FDA regulations relative to a participant's right to petition for issuance amendment or repeal of a rule.

**DATES:** Submit written comments on the collection of information by (*insert date 60 days after date of publication in the **Federal Register***).

**ADDRESSES:** 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 comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

**Citizen Petition—21 CFR 10.30 (OMB Control Number 0910–0183—Extension)**

The Administrative Procedures Act (5 U.S.C. 553(e)) provides that every agency shall accord any interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) provides that any person may submit to the agency a citizen petition requesting the Commissioner of Food and Drugs to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The information is used by the agency to determine the need or desirability of the requested action and also to determine if the submitted information is sufficient to support the action. FDA

determines if the submitted information is sufficient to support the action. FDA determines whether or not to grant the petition based on the information submitted.

The affected respondents are individuals or households, State or local governments, nonprofit institutions and businesses or other for-profit institutions or groups.

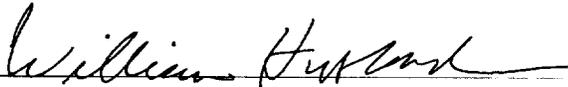
FDA estimates the burden of this collection of information as follows:

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	120	1	120	12	1,440

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

Dated: August 6, 1999



William K. Hubbard

Senior Associate Commissioner for Policy, Planning and Legislation

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