

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0472]

SMB

Display Date	9-22-00
Publication Date	9-25-00
Certifier	S. Reese

Agency Information Collection Activities; Proposed Collection; Comment Request; Petition for Administrative Stay of Action

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 requirements for filing a petition for administrative stay of action.

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

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezuto, 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.

Petition for Administrative Stay of Action—21 CFR 10.35 (OMB Control Number 0910–0194)—Reinstatement)—Extension

The regulations in 21 CFR 10.35, issued under the authority of section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)), set forth the format and procedures by which an interested person may file a petition for an administrative stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action. Such a petition must: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3)

a statement of the factual and legal grounds on which the interested person relies in seeking the stay. The information provided in the petition is used by the agency to determine whether the requested stay should be granted.

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
10.35	13	1	13	10	130

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

The burden estimate for this collection of information is based on FDA's experience with petitions for administrative stay of action over the past 3 years. Agency personnel responsible

for processing the filing of petitions for administrative stays of action estimate that 13 such petitions are received by the agency annually, with each requiring approximately 10 hours of preparation time.

Dated: September 19, 2000



William K. Hubbard
Senior Associate
Commissioner for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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