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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4068]

Agency Information Collection Activities: Proposed Collection; Comment Request; Advisory Opinions; Extension

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 parties seeking an advisory opinion from the Commissioner of Food and Drugs (the Commissioner).

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 below.

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.

Advisory Opinions—21 CFR 10.85 (OMB Control Number 0910–0193—Extension)

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), provides that an interested person may request an advisory opinion from the Commissioner on a matter of general applicability. Section 10.85 sets forth the format and instructions for making an advisory opinion request. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested and a full statement of the facts and legal points relevant to the request. An advisory opinion represents the formal position of FDA on a matter of general applicability.

Respondents to this collection of information are parties seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

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

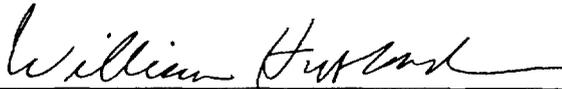
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.85	3	1	3	16	48

¹ There 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 an average for the period 1996 through 1998 with each advisory opinion requiring an estimated 16 hours of preparation time.

Dated: 9/22/99
September 22, 1999



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

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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