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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-4068]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Advisory Opinions**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**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:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**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 of Food and Drugs (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.

In-the **Federal Register** of September 28, 1999 (64 FR 52329), the agency requested comments on the proposed collection of information. No significant comments were received.

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

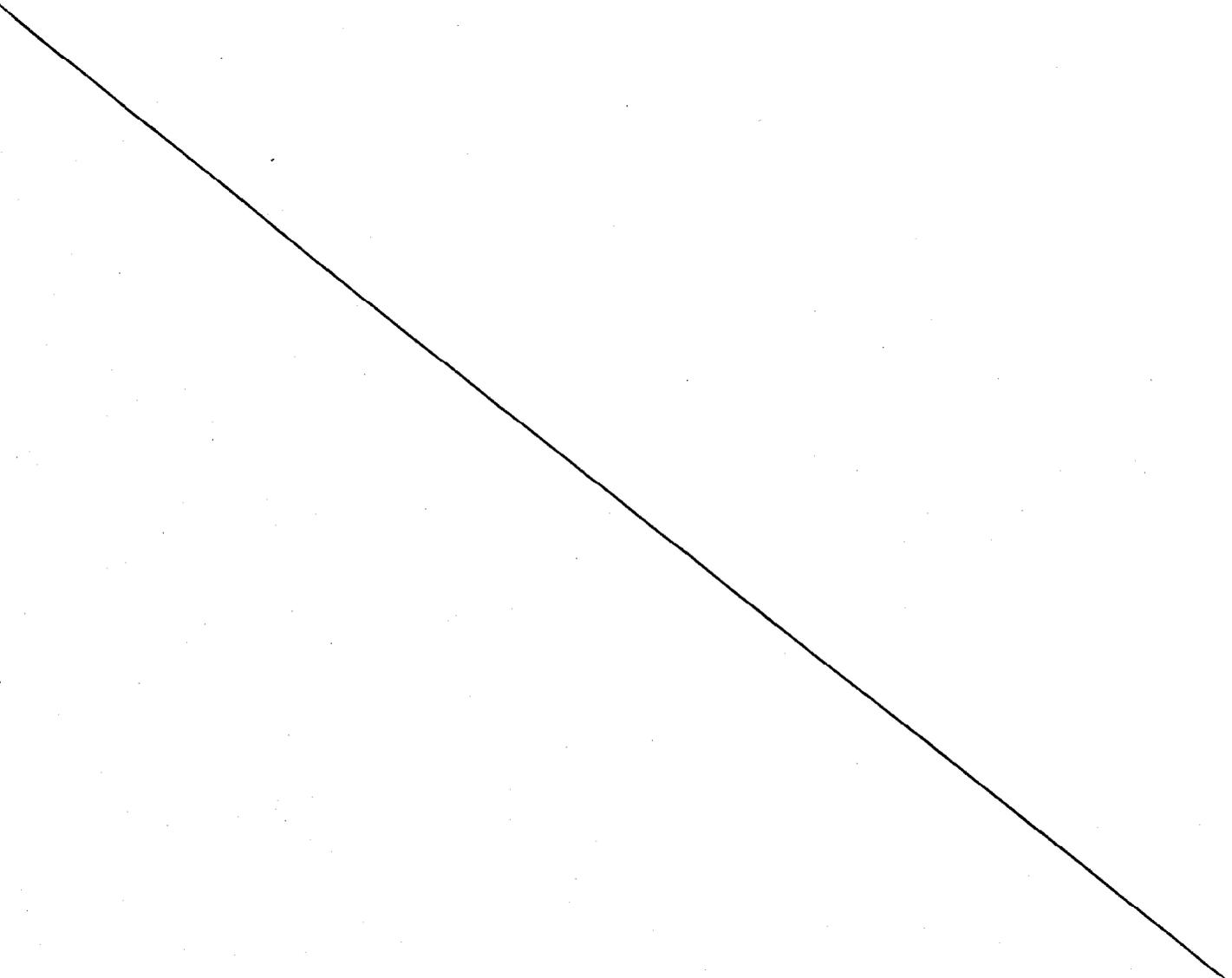


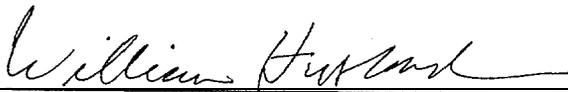
TABLE 1 .-ESTIMATED ANNUAL REPORTING BURDEN'

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

<sup>1</sup> 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: December 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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