

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1674]

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DMB

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Certifier	<u>Domena Oliver</u>

Agency Information Collection Activities; Proposed Collection; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling; Comment Request

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 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 the "Geriatric Use" subsection in the labeling for human prescription drugs.

DATES: Submit written comments 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: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

**Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling (OMB Control Number 0910-0370)—
Extension**

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the "Precautions" section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric

patients (aged 65 and over). The information collection burden imposed by this regulation consists of designing, testing, and submitting the geriatric use subsection of the labeling. The regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

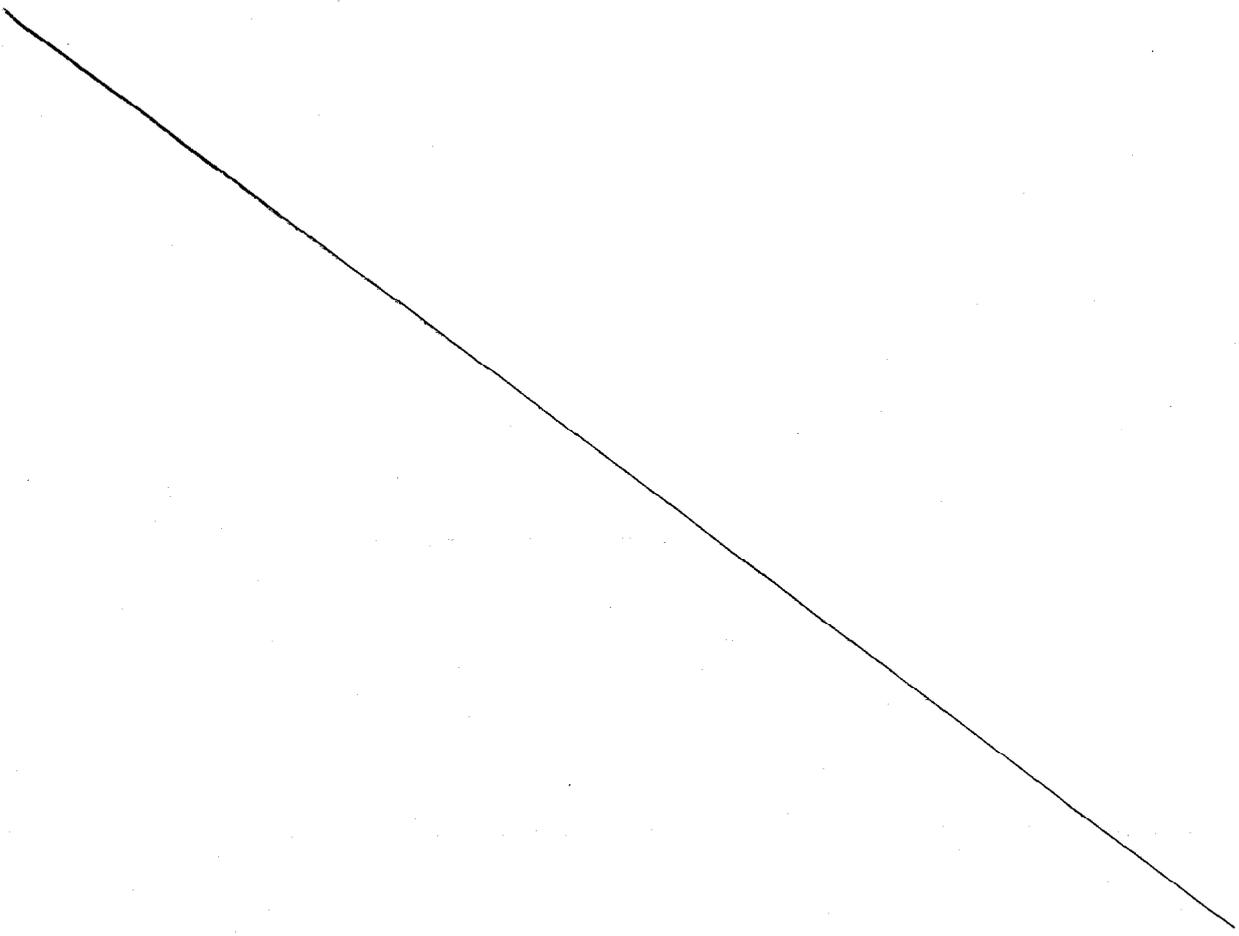


TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—new drug applications	83	1.49	124	8	992
201.57(f)(10)—abbreviated new drug applications	117	3.96	464	2	928
Total					1,920

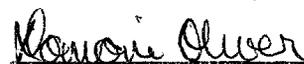
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 28, 2000



Margaret M. Dotzel,
Associate Commissioner for Policy.

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