

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0079]

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Certifier D. Hawkins

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs of Geriatric Use Subsection in the Labeling**

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

**ACTION:** Notice.

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

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

**ADDRESSES:** The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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.

**Specific Requirements on Content and Format of Labeling for Human Prescription Drugs 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 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.

Section 201.57(f)(10) requires that a specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the “Indications and Usage” section of the labeling, and appropriate geriatric dosage must be stated under the “Dosage and Administration” section of the labeling. The “Geriatric use” subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. The data summarized in this subsection of the labeling must be discussed in more detail, if appropriate, under “Clinical Pharmacology” or the “Clinical Studies” section. As appropriate, this information must also be contained in “Contraindications,” “Warnings,” and elsewhere in “Precautions.” Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric

indication, must be contained in the “Geriatric use” subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. These statements are described

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10) NDAs	73	1.48	108	a	864
201.57(f)(10) ANDAs	96	4.67	449	2	898
Total					1,762

Dated: 6/14/04

*Jeffrey Shuren*

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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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