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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	J. M. Williams

Food and Drug Administration

[Docket No. 98D-1169]

Draft Guidance for Industry on Content and Format for Geriatric Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Content and Format for Geriatric Labeling." FDA established the "Geriatric use" subsection in the labeling for human prescription drug products in a final rule. The Geriatric use subsection includes biological drug products in order to provide for the inclusion of information pertinent to the appropriate use of drugs in the elderly (persons aged 65 and over). This draft guidance is intended to provide industry with information on submitting geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in proposed labeling, the content and format for geriatric labeling, and the applicability of user fees to geriatric labeling supplements.

DATES: Written comments may be submitted on the draft guidance by (*insert date 60 days after date of publication in the **Federal Register***). General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or "<http://www.fda.gov/cber/guidelines.htm>". Submit written requests for single copies of "Content and Format for Geriatric Labeling" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers

Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Diana M. Hernandez, Center for Drug Evaluation and Research (HFD-006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6779; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), 1401 Rockville Pike, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled "Content and Format for Geriatric Labeling." This draft guidance has been developed in response to a final rule that published in the **Federal Register** of August 27, 1997 (62 FR 45313), establishing, in the "Precautions" section of prescription drug labeling, a subsection on the use of drugs in elderly or geriatric patients (aged 65 years or over) (§ 201.57(f)(10) (21 CFR 201.57(f)(10))). The geriatric labeling regulation recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in the elderly that are significantly different from those produced in younger patients. Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age and the significant use of medications by this age group.

This draft guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs (§ 201.57(f)(10)(i) through (f)(10)(vi)) that outline

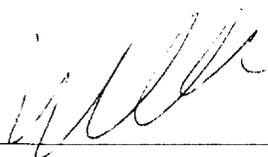
various options for statements in the "Geriatric use" subsection, based on the type of information available and the interpretation of that information. The draft guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi), and it provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the draft guidance document.

This draft guidance is a level 1 draft guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the content and format of geriatric labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999
January 13, 1999



William K. Hubbard
Associate Commissioner
for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.



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