



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1621]

Geriatric Information in Human Prescription Drug and Biological Product Labeling; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Geriatric Information in Human Prescription Drug and Biological Product Labeling.” This draft guidance is intended to assist applicants of human prescription drug and biological products in determining the appropriate placement and content of geriatric information in labeling. The goal of this draft guidance is to provide recommendations to help ensure that appropriate information on the use of prescription drugs and biological products in geriatric patients is consistently placed in the proper sections and subsections within labeling so that the information is clear and accessible to health care practitioners and includes content that guides the safe and effective use in geriatric patients. This draft guidance provides additional examples of geriatric use statements in labeling and examples of when the labeling regulations authorize FDA to permit applicants to omit or revise specific information otherwise required in the *Geriatric Use* subsection. We are withdrawing the guidance for industry entitled “Content and Format for Geriatric Labeling” (October 2001) and replacing it with this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2020-D-1621 for “Geriatric Information in Human Prescription Drug and Biological Product Labeling.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Eric Brodsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993-0002, 301-796-0855; or Stephen Ripley, Center for Biologics

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Geriatric Information in Human Prescription Drug and Biological Product Labeling.”

Until the late 1990s, the majority of drug labeling contained minimal or no geriatric use information to guide safe and effective use in the geriatric population. In 1997, the FDA issued a final rule creating a *Geriatric Use* subsection of labeling to facilitate access to geriatric use information and improve the safe and effective use of prescription drugs and biological products in geriatric patients by specifying a location for summarizing geriatric use information in labeling (62 FR 45313, August 27, 1997). This regulation was intended to promote the consistent inclusion of all relevant geriatric information in labeling and to provide information on possible differences in the safety, effectiveness, pharmacodynamics, and/or pharmacokinetics between geriatric and younger adult patients in labeling.

In 2001, the FDA issued the now-withdrawn guidance for industry entitled “Content and Format for Geriatric Labeling,” which provided recommendations on the content and format of geriatric use information in the *Geriatric Use* subsection in the PRECAUTIONS section. In 2006, FDA published a final rule amending the requirements for the content and format of labeling for human prescription drug and biological products (71 FR 3922, January 24, 2006). This rule is known as the *physician labeling rule* because it addresses prescription drug labeling that is used by physicians and other health care practitioners. Under this rule, the *Geriatric Use* subsection was relocated in the USE IN SPECIFIC POPULATIONS section of labeling.

This draft guidance replaces the withdrawn guidance for industry entitled “Content and Format for Geriatric Labeling” and provides additional examples of geriatric use statements in labeling and examples of when the regulations authorize FDA to permit applicants to omit or revise specific information otherwise required in the *Geriatric Use* subsection.

This draft guidance provides recommendations on how to incorporate geriatric use information in labeling based on the following two scenarios:

- Scenario 1: the drug is approved for use in adult patients generally, including geriatric patients or a subset of the geriatric population or
- Scenario 2: the drug is approved for a geriatric-specific indication [i.e., for a specific indication, the drug is indicated for use only in geriatric patients (or a subset of the geriatric population) and not in younger adult patients]

The *Geriatric Use* subsection of labeling regulations (21 CFR 201.57(c)(9)(v)) uses a variety of terms to refer to patients 65 years of age and older (e.g., *geriatric patients*, *elderly patients*, *persons 65 years of age and older*). Some terms may be sensitive or controversial among certain groups. Please comment and provide a rationale for the use of any of these terms or other terms to refer to patients 65 years of age and older in labeling.

This draft guidance provides several recommended options for summarizing geriatric exposure information in the *Geriatric Use* subsection. Please comment and provide a rationale for the use of any of these geriatric exposure examples or other geriatric exposure examples. Please describe when binning, nested cutoff, or other approaches should be used to summarize geriatric exposure information in this subsection.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

thinking of FDA on the “*Geriatric Information in Human Prescription Drug and Biological Product Labeling*.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collection of information in 21 CFR 201.56 and 201.57 for preparing and submitting labeling has been approved under OMB control number 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: September 10, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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