

“Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 to the Office of

Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:** Iris Masucci, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-2500; 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FDA is announcing the availability of a draft guidance for industry entitled “Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” This draft guidance provides recommendations on the general principles to consider when drafting the DRUG ABUSE AND DEPENDENCE section of the labeling, and how to write, organize, and format the information within the DRUG ABUSE AND DEPENDENCE section of the labeling. The draft guidance provides recommendations on what information to include in the DRUG ABUSE AND DEPENDENCE section, including common terminology and definitions related to abuse and dependence, and how information related to topics presented in the DRUG ABUSE AND DEPENDENCE section should be distributed elsewhere in labeling.

This draft guidance is one in a series of guidances FDA is developing or has developed to assist applicants with the content and format of labeling for

human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and additional guidances on labeling can be accessed at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

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 “Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” 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. This guidance is not subject to Executive Order 12866.

### **II. The 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. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572; the collections of information in 21 CFR 312.41 have been approved under OMB control number 0910-0014; the collections of information in 21 CFR 314.126(c), 314.70, and 314.97 have been approved under OMB control number 0910-0001; and the collections of information in 21 CFR 601.12 have been approved under OMB control number 0910-0338.

### **III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: June 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-14061 Filed 7-1-19; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2019-D-1615]

#### **Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, 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 “Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format.” This draft guidance provides recommendations for developing the content and format of an Instructions for Use (IFU) document for human prescription drugs and biological products and drug-device or biologic-device combination products submitted under a new drug application (NDA) or a biologics license application (BLA). The IFU is developed by applicants for patients who use drug products that have complicated or detailed patient-use instructions. The recommendations in this draft guidance are intended to help develop consistent content and format across IFUs and to help ensure that patients receive clear, concise information that is easily understood for the safe and effective use of prescription drug products.

**DATES:** Submit either electronic or written comments on the draft guidance by September 3, 2019 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-2019-D-1615 for "Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format." 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.

- **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.gpo.gov/fdsys/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.

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

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#### FOR FURTHER INFORMATION CONTACT:

Chris Wheeler, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993, 301-796-0151; 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, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format." The recommendations in this guidance are intended to help develop consistent content and format across IFUs and to help ensure that patients receive clear, concise information that is easily understood for the safe and effective use of such prescription drug products.

The IFU is a form of prescription drug labeling submitted under a new drug application (NDA), biologics license application (BLA), or abbreviated new drug application (ANDA). The IFU is developed by applicants for patients who use drug products that have complicated or detailed patient-use instructions. For example, an IFU may be appropriate for a drug product with one set of dosing instructions for adult patients and another set for pediatric patients. The IFU is developed by the applicant, reviewed and approved by FDA, and provided to patients when the drug product is dispensed.

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 "Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format." 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. This guidance is not subject to Executive Order 12866.

## 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. 3501-3520). The collections of information in 21 CFR part 201 have been approved under OMB control number 0910-0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>; <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>; <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>; or <https://www.regulations.gov>.

Dated: June 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-6069]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; De Novo Classification Process (Evaluation of Automatic Class III Designation)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) 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 August 1, 2019.

**ADDRESSES:** 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: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0844. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**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.

#### De Novo Classification Process (Evaluation of Automatic Class III Designation)

OMB Control Number 0910-0844—Revision

The draft guidance entitled “Acceptance Review for De Novo Classification Requests” (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-review-de-novo-classification-requests>) explains the procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. The draft guidance discusses De Novo acceptance review policies and procedures, “Refuse to Accept” principles, and the elements of the De Novo Acceptance Checklist and the Recommended Content Checklist and was issued to be responsive to an explicit deliverable identified in the Medical Device User Fee Amendments of 2017.

To aid in the acceptance review, the guidance recommends that requesters complete and submit with their De Novo request an Acceptance Checklist that identifies the location of supporting information for each acceptance element and a Recommended Content Checklist that identifies the location of supporting information for each recommended content element. Therefore, we request revision of OMB control number 0910-0844, “De Novo Classification Process (Evaluation of Automatic Class III Designation)” to include the Acceptance Checklist and the Recommended Content Checklist in the hourly burden estimate for De Novo requests.

Respondents to the information collection are medical device manufacturers seeking to market medical device products through submission of a De Novo classification request under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)).

In the **Federal Register** of October 30, 2017 (82 FR 50135), FDA published a 60-day notice requesting public comment on the draft guidance and the proposed collection of information. We received various comments on the draft guidance. We describe and respond to the comments related to the proposed

information collection in the following paragraphs. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same set of comments and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment’s value or importance or the order in which comments were received.

(Comment 1) One comment proposed that, in section VII.B of the draft guidance (“Prior Submission(s) Relevant to the De Novo Request Under Review”), FDA revise the phrase “For certain De Novo requests, the requester may have previously provided other submissions for the same device for which FDA provided feedback related to the data or information needed to support De Novo classification (e.g., a pre-submission request, investigational device exemption, prior Not Substantially Equivalent (NSE) determination, or prior 510(k) or De Novo that was deleted or withdrawn)” to read, “For certain De Novo requests, the requester may have previously provided other submissions, or there may be related FDA correspondence or other relevant information for the same device, for which FDA provided feedback related to the data or information needed to support De Novo classification . . .” The commenter noted that there may be informal correspondence that is pertinent to the De Novo and this should be explicitly requested in the “Recommended Content Checklist” in Appendix B.

(Response 1) FDA does not agree with the proposed revision. This element was intended to specifically focus on pertinent premarket submissions and formal communications that have undergone supervisory review.

(Comment 2) One comment suggested that elements identified as “N/A” should require an accompanying rationale because an inadvertent selection of a N/A answer may result in a “Refuse to Accept” (RTA) decision.

(Response 2) We do not agree with this comment. Selection of “N/A” for any element would not lead to an RTA decision. As explained in section VI.C of the guidance, “. . . the item should receive an answer of “yes” or “N/A” for the De Novo request to be accepted for substantive review.”

(Comment 3) Two commenters suggested that the preliminary questions in Appendix A (“Acceptance Checklist