issuer offering group or individual health insurance coverage. *Form Number:* CMS–10788 (OMB control number: 0938–1405); *Frequency:* Annual; *Affected Public:* Private Sector; *Number of Respondents:* 356; *Total Annual Responses:* 356; *Total Annual Hours:* 1,684,080. (For policy questions regarding this collection, contact Christina Whitefield at 301–492–4172.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations; *Use:* The transitional pass-through provision provides a way for ensuring appropriate payment for new technologies whose use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed as required by law. Categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payments are initiated for the category. However, the underlying provision is permanent and provides an on-going mechanism for reflecting timely introduction of new items into the payment structure.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional pass-through payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. The following information is required to process requests for additional categories of medical devices for transitional pass-through payments. *Form Number:* CMS–10052 (OMB control number: 0938–0857); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 10; *Number of Responses:* 10; *Total Annual Hours:* 160. (For questions regarding this collection contact Kimberly A. Campbell at 410–786–2289.)

4. *Type of Information Collection Request:* Revision of a currently approved collection: *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Use:* Form CMS–460 is the agreement a physician, supplier, or their authorized official signs to become a participating provider in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term ''supplier'' means certain other persons or entities, other than physicians, that may bill Medicare for Part B services (*e.g.,* suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered ''suppliers'' for purposes of this agreement. *Form Number:* CMS–460 (OMB control number: 0938–0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 36,000; *Number of Responses:* 36,000; *Total Annual Hours:* 9,000. (For questions regarding this collection contact Mark G. Baldwin at 410–786–8139.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Implementation of the In-Center Hemodialysis CAHPS Survey; *Use:* The national implementation of the ICH CAHPS Survey is designed to allow third-party, CMS-approved survey vendors to administer the ICH CAHPS Survey using mail-only, telephone-only, or mixed (mail with telephone follow-up) modes of survey administration. Experience from previous CAHPS surveys shows that mail, telephone, and mail with telephone follow-up data collection modes work well for respondents, vendors, and health care providers. Any additional forms of information technology, such as web surveys, is under investigation as a potential survey option in this population.

Data collected in the national implementation of the ICH CAHPS Survey are used for the following purposes:

- To provide a source of information from which selected measures can be publicly reported to beneficiaries as a decision aid for dialysis facility selection.
- To aid facilities with their internal quality improvement efforts and external benchmarking with other facilities.
- To provide CMS with information for monitoring and public reporting purposes.
- To support the ESRD Quality Improvement Program.

*Form Number:* CMS–10105 (OMB control number: 0938–0926); *Frequency:* Semi Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 103,500; *Total Annual Responses:* 621,000; *Total Annual Hours:* 55,890. (For policy questions regarding this collection contact Israel H. Cross at 410–786–0619.)

Dated: July 12, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2022–15175 Filed 7–14–22; 8:45 am]

**BILLING CODE 4120–01–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—Content and Format; 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 final guidance for industry entitled ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This guidance provides recommendations for developing the content and format of an Instructions for Use (IFU) document for human prescription drug and biological products, as well as drug-led or biologic-led combination products submitted under a new drug application (NDA) or a biologics license application (BLA). The IFU is written for patients (or their caregivers) who use drug products that have complicated or detailed patient-use instructions. The recommendations in this guidance are intended to help ensure that patients receive clear and concise information that is easily understood for the safe and

effective use of such products. This guidance finalizes the draft guidance issued on July 2, 2019, entitled ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format.''

**DATES:** The announcement of the guidance is published in the **Federal Register** on July 15, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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.'' 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 this 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, 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 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 guidance for industry entitled ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The recommendations in this guidance are intended to help ensure that patients receive clear and concise information that is easily understood for the safe and effective use of such products and to help provide consistency to the content and format of IFU documents.

The IFU is a form of prescription drug labeling. For drugs for which self-administration may be complicated (such as requiring the patient to perform multiple steps to prepare, administer, store, and/or dispose of the drug), the IFU is intended to give directions that are clear and understandable for patients, and therefore, promote the safe and effective use of that drug. For example, IFUs 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 guidance finalizes the draft guidance entitled ''Instructions for Use—Patient Labeling for Human Prescription Drug and Biological Products and Drug-Device and Biologic-Device Combination Products—Content and Format,'' issued on July 2, 2019 (84 FR 31598). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include a change in title in addition to editorial changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Instructions for Use—Patient 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.

**II. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. 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 guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 8, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–15161 Filed 7–14–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3031]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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:** Submit written comments (including recommendations) on the collection of information by August 15, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0749. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@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.

**Tobacco Products, User Fees, Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products**

*OMB Control Number 0910–0749—Extension*

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

FDA issued a final rule on May 10, 2016 (81 FR 28707) that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10688.pdf*). FDA expanded its authority over tobacco products by issuing another final rule entitled ''Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products'' (Deeming rule; May 10, 2016, 81 FR 28974), deeming all products that meet the statutory definition of ''tobacco product,'' except accessories of the newly deemed tobacco products, to be subject to the FD&C Act (*https://www.govinfo.gov/content/pkg/FR-2016-05-10/pdf/2016-10685.pdf*). The Deeming rule, among other things, subjected domestic manufacturers and importers of cigars and pipe tobacco to the FD&C Act's user fee requirements. Consistent with the Deeming rule and the requirements of the FD&C Act, the user fee final rule requires the submission of the information needed to calculate user fee assessments for each manufacturer and importer of cigars and pipe tobacco to FDA.

As noted, FDA issued a final rule that requires domestic tobacco product manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the FD&C Act. The U.S. Department of Agriculture (USDA) had been collecting this information and provided FDA with the data the Agency needed to calculate the amount of user fees assessed to tobacco product manufacturers and importers. USDA ceased collecting this information in fiscal year 2015 (October 2014). USDA's information collection did not require OMB approval, per an exemption by Public Law 108–357, section 642(b)(3). Consistent with the requirements of the FD&C Act, FDA requires the submission of this information to FDA. FDA took this action to ensure that the Agency continues to have the information needed to calculate, assess, and collect