

reclassification order published in the **Federal Register** following

consideration of comments and any panel recommendations or comments.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR section; information collection activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| § 860.123; supporting data for reclassification petitions | 6 | 1 | 6 | 497 | 2,982 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19221 Filed 9–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0944]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled “Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” The document announced a meeting of the Pediatric Advisory Committee. The document was published with the incorrect docket number and end time of the meeting. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, August 10, 2021, in FR Doc. 2021–16984 (86 FR 43666), the following corrections are made.

1. On page 43666, in the first column, in the header of the document, and in

the third column under “Instructions,” “Docket No. FDA–2020–N–1648N” is changed to “Docket No. FDA–2021–N–0944”.

2. On page 43666, in the first column, the DATES portion of the document is changed to: “The meeting will be held on September 17, 2021, from 10 a.m. to 3 p.m. Eastern Time.”

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19216 Filed 9–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0918]

Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with labeling requirements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by November 8, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 8, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 8, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Docket No. FDA-2021-N-0918 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Labeling Requirements for Prescription Drugs and Biological Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Labeling Requirements for Prescription Drugs

OMB Control Number 0910-0572—Revision

This information collection supports FDA regulations governing the labeling of prescription drugs. The regulations are codified in 21 CFR part 201, subpart B (21 CFR 201.50 through 201.58) and set forth both general requirements, as well as specific content and format requirements. The regulations also provide for requesting a waiver from any labeling requirement and do not apply to biological products that are subject to the requirements of section 351 of the Public Health Service Act.

We are revising the information collection to include burden associated with regulations applicable to medical gas labeling found in § 201.328 (21 CFR 201.328) and established by a final rule in the **Federal Register** of November 18, 2016 (81 FR 81685 at 81694). While we included corresponding changes and adjustments resulting from the final rule to the information collection approved under OMB control number 0910-0139 as it pertains to good manufacturing practice requirements and regulations in part 211 (21 CFR part 211), we did not make corresponding changes and adjustments to this information collection with regard to burden that may be associated with labeling requirements found in § 201.328 (81 FR 81685 at 81694).

To assist respondents with the information collection we continue to develop and issue guidance documents, available from our searchable guidance database at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. All Agency guidance documents are issued consistent with our good guidance practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Activity/21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Labeling requirements for prescription drugs; §§ 201.56 and 201.57. | 414 | 1.326 | 549 | 3,349 | 1,838,601 |
| Labeling of medical gas containers; § 201.328 | 260 | 1,663 | 432,380 | 0.17 (10 minutes) .. | 43,238 |

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

| Activity/21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Total | | | 432,929 | | 1,881,839 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

New drug product and biological product applicants must: (1) Design and create prescription drug labeling containing “Highlights,” “Contents,” and “Full Prescribing Information”; (2) test the designed labeling (for example, to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on our experience with the information collection, we estimate 414 applicants will prepare an average of 549 prescription drug labels and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application. Similarly, new medical gas containers must meet applicable requirements found in part 211, as well as specific labeling requirements in § 201.328. We estimate that 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as required under § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Our estimated burden for the information collection reflects an overall increase resulting from an increase in submissions for new product labeling as well as from the revision to include burden associated with requirements in § 201.328.

Dated: August 31, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–19218 Filed 9–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0965]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

Consistent with FDA’s regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This **Federal Register** notice could not be published 15 days prior to the date of the meeting due to a recent submission of a request to supplement the approved Biologics License Application for COMIRNATY for administration of a third dose, or “booster” dose, of the COVID–19 vaccine, in individuals 16 years of age and older and the need for prompt discussion of such submission given the COVID–19 pandemic.

DATES: The meeting will be held on September 17, 2021, from 8:30 a.m. to 3:45 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/WFph7-6t34M>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0965. The docket will close on September 16, 2021. Submit either electronic or written comments on this public meeting by September 16, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 16, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2021. Comments received by mail/hand delivery/courier (for

written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 13, 2021, will be provided to the committee. Comments received after September 13, 2021, and by September 16, 2021, will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

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- For written/paper comments submitted to the Dockets Management