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

¹There 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.