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–1518 for ''Development of Anti-Infective Drug Products for the Pediatric Population.'' 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 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: Hiwot Hiruy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0872; 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 final guidance for industry entitled ''Development of Anti-Infective Drug Products for the Pediatric Population.'' The purpose of this guidance is to provide general recommendations on the development of anti-infective drug products for pediatric patients. The guidance addresses enrollment strategies, extrapolation of efficacy, safety database, and other considerations to help facilitate pediatric anti-infective drug product development.

This guidance finalizes the draft guidance of the same title issued on June 30, 2020 (85 FR 39193). FDA provided clarifying edits to the final guidance and included additional information after considering comments received on the draft guidance. Changes from the draft to the final guidance include updates to efficacy extrapolation from adult to pediatric patients (including from one pediatric subpopulation to another), safety data collection, additional considerations for studies, and recommendations for conducting juvenile toxicology studies.

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 ''Development of Anti-Infective Drug Products for the Pediatric Population.'' 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 parts 312 and 314 and 21 CFR 201.56 and 201.57 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0572, respectively.

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/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26737 Filed 12–9–21; 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; Submission for Office of Management and Budget Review; 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 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 January 10, 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 0910–0572. Also include the FDA docket number found in brackets in the heading of this document.

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, *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.

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.

In the **Federal Register** of September 7, 2021 (86 FR 50134), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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)	73,505
Total			432,929		1,912,106

[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: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26730 Filed 12–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1096]

Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment; 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 ''Chronic Rhinosinusitis with Nasal Polyps: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of drugs for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). Specifically, this