Dated: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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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; 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 ''Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of drugs or biological products for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP). Specifically, this guidance addresses FDA's current thinking regarding trial population and design, effectiveness, statistical analysis, and safety for drugs being developed for the treatment of CRSwNP. This guidance finalizes the draft guidance of the same title issued on December 10, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on June 30, 2023.

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–2021–D–1096 for ''Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.'' 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: Rekha Jhamnani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3395, Silver Spring, MD 20993–0002, 301–796–5636; or Diane Maloney, 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 guidance for industry entitled ''Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.'' The guidance provides recommendations for sponsors developing products for the treatment of CRSwNP. Specifically, this guidance represents FDA's current thinking regarding trial population and design, effectiveness, statistical analysis, and safety for drugs being developed for the treatment of CRSwNP. This guidance does not address the clinical development of drugs for the treatment

of chronic rhinosinusitis without nasal polyps or allergic fungal rhinosinusitis.

This guidance finalizes the draft guidance of the same title issued on December 10, 2021 (86 FR 70505). FDA considered comments received on the draft guidance in this finalized guidance. Chronic rhinosinusitis is characterized by inflammation of the nasal mucosa and paranasal sinuses and can be further divided into chronic rhinosinusitis with and without nasal polyps. Nasal polyps are inflammatory hyperplastic growths that protrude into the nasal passages. Symptoms of CRSwNP include nasal congestion, nasal discharge, facial pain or pressure, and loss of smell. Nasal polyps have associated morbidity that can have substantial impact on day-to-day functioning. Because of differences in natural history and treatment between chronic rhinosinusitis with and without nasal polyps, this guidance specifically addresses aspects of trial design, safety and efficacy assessment for CRSwNP. Changes from the draft to the final guidance include considerations for efficacy assessments for CRSwNP.

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 ''Chronic Rhinosinusitis With Nasal Polyps: Developing Drugs for Treatment.'' 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 contained in 21 CFR part 312 relating to investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to new drug applications have been approved under OMB control number 0910–0001. The collections of information contained in 21 CFR part 601 relating to biologics license applications 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: June 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0438]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 29, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: FY2020 Teen Pregnancy Prevention (TPP) Program Performance Measures.

Type of Collection: Extension.

OMB No.: 0990–0438.

Abstract: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health (OASH), U.S. Department of Health and Human Services (HHS), requests a renewal clearance for the collection of performance measures specifically for FY2020 Teen Pregnancy Prevention (TPP) Program grantees. Collection of performance measures is a requirement of all TPP awards and is included in the NOFOs. The data collection will allow OPA to comply with federal accountability and performance requirements, inform stakeholders of grantee progress in meeting TPP program goals, provide OPA with metrics for monitoring TPP grantees, and facilitate individual grantees' continuous quality improvement efforts within their projects. OPA requests clearance for one year to cover reporting during the no-cost extension period of the awards.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Grantees (partners and sustainability)	All TPP grantees	90	2	15/60	45
Grantees (training)	All TPP Grantees	90	2	15/60	45
Grantees (dissemination)	All TPP Grantees	90	2	30/60	90
Grantees (Stakeholder Engagement)	All TPP Grantees	90	2	15/60	45
Grantees (Reach and Demographics)	Tier 1 and Tier 2 Phase II Grantees	64	2	3	384
Grantees (Dosage)	Tier 1 and Tier 2 Phase II Grantees	64	2	2	256
Grantees (Fidelity and Quality)	Tier 1 and Tier 2 Phase II Grantees	64	2	2	256