TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Phone Survey	17	1	17	0.5 (30 minutes)	9
Online Survey	56	1	56	1	56
Total					65

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest hour.

The targeted groups for this collection of information include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Pub. L. 110–85; 42 U.S.C. 282 note), and trade organizations, medical provider organizations, organizations and individuals involved with financing and reimbursement associated with medical devices, pediatric healthcare leaders, clinicians who regularly use medical devices in caring for children, and organizations and individuals representing patients and consumers.

Phone survey: Respondents participating in the phone survey will be executives from companies either producing products in pediatrics or from companies that produce products that could be used in pediatrics. Executives will be invited to engage in the 30-minute phone survey.

Online survey: The 1-hour online survey will be administered to leaders within pediatric companies and key decision makers in the pediatric medical device industry (*e.g.,* venture capitalists, banking investors, leaders in children's hospitals and research networks, and pediatric patient advocates).

Substantial turnover in the graduate students administering the survey made it necessary to bring in a new cohort of students and train them in the issues relevant to the survey. As a result, we were unable to field the B12 Pediatrics survey before the OMB approval expiration date and are seeking a reinstatement to complete data collection. To better ensure timely completion of the data collection, the Yale CERSI team has shifted responsibility for conducting the survey and other aspects of the study to a Yale Staff Associate Research Scientist.

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 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19865 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1530]

Control of Nitrosamine Impurities in Human Drugs; 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 ''Control of Nitrosamine Impurities in Human Drugs.'' This guidance recommends steps manufacturers of active pharmaceutical ingredients (APIs) and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products. The guidance describes two general structural classes of nitrosamine impurities: small-molecule nitrosamine impurities (*i.e.,* nitrosamine impurities that do not share structural similarity to the API), and nitrosamine drug substance-related impurities (NDSRIs), which share structural similarity to the API and are generally unique to each API. The potential root causes of small-molecule nitrosamine impurities and NDSRI formation, detection of nitrosamine impurities, and recommendations for risk assessments, testing, and implementation of controls and other appropriate strategies to prevent or reduce the presence of small-molecule nitrosamine impurities and NDSRIs are provided. This guidance revises the final guidance of the same name issued on February 24, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on September 5, 2024.

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–2020–D–1530 for ''Control of Nitrosamine Impurities in Human Drugs; Guidance for Industry; Availability.'' 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. 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: Susan Zuk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6684, Silver Spring, MD 20993–0002, 240–402–9133, *susan.zuk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Control of Nitrosamine Impurities in Human Drugs.'' FDA is issuing this guidance consistent with its good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). FDA is implementing this guidance without prior public comment because it has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115(g)(2)). FDA made this determination because of the importance of providing timely information to manufacturers and applicants regarding nitrosamine impurities, and the resulting recommendations to conduct risk assessments, testing, and other appropriate actions to prevent or reduce the presence of nitrosamine impurities, including NDSRIs, in APIs and drug products. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation. This guidance recommends steps manufacturers of APIs and drug products should take to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products. The guidance also describes conditions that may introduce nitrosamine impurities. The unexpected finding of nitrosamine impurities, which are possible and probable human carcinogens, in certain drug products has made clear the need for a risk assessment strategy for potential nitrosamines in any pharmaceutical product at risk for their presence.

This guidance revises the final guidance of the same title issued on February 24, 2021. The following changes were made to the guidance:

• The guidance describes two general structural classes of nitrosamine impurities: small-molecule nitrosamine impurities (*i.e.,* nitrosamine impurities that do not share structural similarity to the API), and NDSRIs, which share structural similarity to the API and are generally unique to each API. NDSRIs are also addressed in the guidance for industry entitled ''Recommended Acceptable Intake Limits for Nitrosamine Drug Substance-Related Impurities (NDSRIs),'' available at *https://www.fda.gov/media/170794/download.* This revision provides additional information on potential root causes of NDSRI formation, controls, and mitigation strategies to prevent or reduce the presence of NDSRIs. This guidance recommends mitigation strategies to reduce or eliminate nitrosamine impurities, and includes new recommendations for stability data and bioequivalence studies to support approval of drug products reformulated using such strategies.

• The guidance provides new recommendations for implementation of nitrosamine impurity control strategies. The guidance clarifies how manufacturers should assess test results to determine whether specifications for nitrosamine impurities are warranted, and provides recommendations for how to report revised specifications, when and how to contact the Agency, and recommended alternative approaches to establishing total nitrosamine impurity limits.

• This guidance provides a recommended timeline for implementation of the recommendations described within. FDA notes that manufacturers and applicants should have completed the 3-step process for evaluating small molecule nitrosamines in their drug products by October 1, 2023. In addition, due to the more recent discovery of NDSRI impurities, FDA recommends conclusion of confirmatory testing of drug products and submission of changes for approved applications that may have NDSRIs by August 1, 2025.

• To reflect the evolving and highly technical nature of the relevant information, FDA intends to provide certain information in an incorporated web page that will be updated, as appropriate, to provide current information in connection with this guidance, including recommended acceptable intake limits, emerging scientific and technical issues, recommended analytical methods for confirmatory testing of certain nitrosamine impurities, recommended safety testing methods for nitrosamine impurities, and recommended timelines for implementing the mitigation recommendations.

This guidance represents FDA's current thinking on ''Control of Nitrosamine Impurities in Human Drugs.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 pertaining to investigational new drug applications, including meetings at the ''pre-NDA'' stage, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to new drug applications, abbreviated new drug applications, amendments and supplemental applications, and formal meetings with FDA about drug development programs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications have been approved under OMB control number 0910–0338. The collections of information pertaining to over-the-counter monograph drug products have been approved under OMB control number 0910–0340. The collections of information pertaining to meetings related to generic drug development, including controlled correspondences, have been approved under OMB control number 0910–0727.

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,* or *https://www.regulations.gov.*

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19883 Filed 9–4–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3762]

Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

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 the information collection associated with FDA research in obtaining information from pharmacists and other management at outsourcing facilities and related human prescription drug compounding businesses. The research supports a comprehensive analysis of the outsourcing facility sector that informs ongoing FDA work in this area.

DATES: Either electronic or written comments on the collection of information must be submitted by November 4, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 the Docket No. FDA–2024–N–3762 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities.'' 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