and reports of the withdrawal of an approved drug from sale under § 314.81(b)(3)(iii).

We estimate 1,000 firms will expend 40 hours to prepare, review, and approve a standard operating procedure (SOP), for a total of 40,000 hours annually. Although we expect most respondents will have already prepared and implemented an SOP for the electronic submission of drug establishment registration and drug listing information, we retain an estimate for new firms that will do so, as recommended in the guidance document.

Additionally, we assume 10,480 registrants, (accounting for both biological product and drug product registrants) are subject to the reporting provisions under section 510(j)(3) of the FD&C Act but exclude 1,780 respondents to reflect the reporting exemptions implemented under section 510(j)(3)(B) pertaining to: (1) blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient. Also, based on informal communications, we have increased the estimated burden we attribute to prepare and submit the requisite information for reporting provisions under section 510(j)(3) of the FD&C Act from 15 minutes to 1 hour.

Regarding notifications to FDA of changes in the production of animal drugs associated with the guidance document entitled ''Reporting and Mitigating Animal Drug Shortages,'' we estimate that 30 respondents will provide two notifications each year and that it will take 1 hour to prepare and submit each notification.

Finally, regarding the information collection associated with the guidance document entitled ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' we assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and estimate each notification requires 16 hours to prepare and submit. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended Plan, and therefore, we limit our current burden estimate to updates and maintenance. Accordingly, we estimate 70 manufacturers will update or maintain the recommended Plan and those changes would take approximately 250 hours per manufacturer.

Our estimated burden for the information collection reflects an overall decrease of 65,934 responses/records but an overall increase of 144,913 hours annually. We attribute adjustments to our reevaluation of the number of submissions we received over the last few years for the provisions in part 207 and the increase in the estimated burden per response to 1 hour to prepare and submit the requisite information for the reporting provisions under section 510(j)(3) of the FD&C Act.

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19862 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–2022–N–1894]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 October 7, 2024.

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 0910–0912. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey

OMB Control Number 0910–0912—Reinstatement

Despite numerous legislative, regulatory, and scientific efforts, there has been little change in the number of devices approved for use in pediatric patients. This has often led to devices being adapted for use in children without an appropriate level of evidence, exposing them to inconsistent benefit risk profiles. This health inequity highlights the need for devices that are designed, evaluated, and labeled for pediatric patients. To address these challenges, this collection is being done to survey industry and other key stakeholders in the medical device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled, ''Pediatric Medical Device Development.'' As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L. 115–52) the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

In the **Federal Register** of May 22, 2024 (89 FR 44993), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

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.''