may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms streamline the refund and transfer processes, facilitate processing, and improve the tracking of refund or transfer requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Respondents are able to request a user fee payment refund or transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913.	1,856	1	1,856	0.40 (24 minutes)	742
User Fee Payment Transfer Request—Form FDA 3914.	86	1	86	0.25 (15 minutes)	22
Total	.....	.....	.....	.....	764

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 525 hours and a corresponding increase of 1,274 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08968 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1057]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications.''

DATES: Either electronic or written comments on the collection of information must be submitted by June 25, 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 June 25, 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–1057 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications.'' 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 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.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pregnancy Exposure Registry Enrollment Project: A Survey of Healthcare Providers To Advance Pregnancy Safety Data Collection and Improve Health Communications

(OMB Control Number 0910—NEW)

I. Background

FDA has a need for data on pregnancy exposure registries (registries). The goal of the proposed Pregnancy Exposure Registry Enrollment Project survey is to determine healthcare providers' (HCPs) perceived barriers to sufficient patient enrollment in pregnancy exposure registries. FDA's authority to conduct research related to drugs and other FDA-regulated products is set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act), (21 U.S.C. 393(d)(2)(C) and (D)).

To ensure that pregnancy information in product labeling is accurately communicated to HCPs so that they can make informed decisions about treatment options for their patients, human pregnancy safety data are collected postapproval. Registries are an important tool for pregnancy safety data collection in the postmarketing setting. Their prospective design and ability to collect detailed patient information are critical to obtain human data to inform pregnancy labeling in a timely manner.

The pharmaceutical industry typically sponsors registries often as a result of a postmarketing requirement (PMR) or commitment (PMC) FDA issues at the time of drug approval under section 505(o)(3) of the FD&C Act (21 U.S.C. 355(o)(3)). Under a PMR or PMC, pharmaceutical industry sponsors often work with private companies, nonprofits, and/or academic health centers to operate registries. Other times, private companies, nonprofits, Federal agencies other than FDA, or academic health centers may develop registries without FDA involvement to facilitate pregnancy-related research with other scientific goals. When developing registry protocols, sponsors and those who operate registries must comply with 45 CFR part 46 and meet the Criteria for IRB approval of research under 45 CFR 46.111, which provides protection of human research subjects, subjects' privacy, and the confidentiality of subjects' data.

Although registries are crucial to understanding the safety and potential toxicity of prescription products in the perinatal population, many registries fail to adequately enroll pregnant individuals. HCPs are a trusted source of information about health, and they serve as gatekeepers for recruiting pregnant individuals to enroll in clinical studies such as registries. Thus, HCPs are integral to the registry enrollment process. Publications suggest that low enrollment in registries may be related to HCPs' lack of awareness, time, incentives, and comfort with discussing clinical research with patients. Despite this speculation about the barriers that HCPs face, however, researchers have not surveyed HCPs to understand their challenges. FDA reviewed existing literature and engaged with other Offices and Centers within FDA and external experts and determined that this data collection is not duplicative.

During this voluntary, FDA-funded, qualitative survey, we will recruit through an existing panel of HCPs currently licensed to practice in clinical settings in the United States who routinely care for or counsel pregnant patients. We will engage three groups of HCPs: (1) primary HCPs (obstetrician/gynecologists, family practice physicians, certified nurse-midwives, physician assistants); (2) consulting HCPs (neurologists, infectious disease specialists, psychiatrists, rheumatologists, cardiologists, pulmonologists, dermatologists), and (3) pharmacists. To be eligible for the study, primary HCPs must routinely care for or counsel five or more pregnant patients per month, and consulting HCPs and pharmacists must routinely care for or counsel three or more pregnant patients per month. All eligible HCPs must have either a degree

as a Doctor of Medicine, a Doctor of Osteopathic Medicine, or a Doctor of Pharmacy. Although we will recruit with representativeness in mind, we will weigh the data to ensure a nationally representative sample of HCPs. Generated tables will compare the weighted distributions of the variables used for weighting against their corresponding benchmarks.

A contracted research firm will collect data through internet administration. One hundred percent (100%) of participants will self-administer the internet survey via a computer, which will record responses and provide appropriate probes when needed. We will use automated technology in data collection, data reduction, and analyses. To identify eligible HCPs, we will send a recruitment email that links to a prequalifying screener on the internet. The screener will include questions about the HCP's specialty, number of years in practice, number of pregnant patients counseled per month, and demographics (age, race/ethnicity, and gender) and will confirm that the respondent does not work for FDA or a pharmaceutical company. We will invite all respondents who meet eligibility requirements to participate in the survey within 24 hours of completing the screener and obtain informed consent from all survey participants. The survey will assess experienced HCPs' knowledge of registries, their attitudes toward them, the barriers they face to recruiting patients, and their ideas about improving registry enrollment. Results from this project will advance pregnancy safety data collection from registries and ultimately improve health communications through inclusion of human safety data in pregnancy labeling. The survey is available on request at *pedsdrugs@fda.hhs.gov.*

We have the following specific research questions:

1. What proportion of HCPs know about pregnancy exposure registries?
2. What proportion of HCPs have referred patients to pregnancy exposure registries?
3. What proportion of HCPs have provided information from patient medical records to pregnancy exposure registries?
4. What barriers to patient enrollment in pregnancy exposure registries are identified by HCPs?
5. What ideas do HCPs have to improve enrollment in pregnancy exposure registries?

The target sample size for this study is 400 completed surveys. The sample will include an equal number of primary HCPs, consulting HCPs, and pharmacists. Such a design will help to ensure assessment of not only HCPs' perceptions generally, but also potential variations between different types of HCPs. HCPs are a difficult group to recruit, so several strategies will be put into place to achieve a high response rate. These strategies include tailoring contact materials, disclosing FDA sponsorship on survey materials, and providing a cash incentive.

To obtain 400 completed surveys, we estimate that 2,000 experienced HCPs will need to be screened. We estimate that participation in the study will take 17 minutes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	2,000	1	2,000	0.0333 (2 minutes)	67
Main Study Survey	400	1	400	0.25 (15 minutes)	100
Total	2,000				167

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Prior to the main analysis, an outlier analysis will be performed for the time spent on any screen visited and total time to complete the survey. Extreme survey time will be identified and appropriate adjustments will be made prior to the final data analysis. The extent of any missing information will also be assessed to determine the data quality. Descriptive statistics will afford a look at the frequency of responses. Assessment of potential differences between primary HCPs, consulting HCPs, and pharmacists can be accomplished with pairwise comparisons between groups. We will also produce national-level estimates about attitudes toward pregnancy exposure registries and other key questions.

An analysis of item nonresponse will be made in the screener, if needed, and in the main survey. Item nonresponse rates will be tabulated for the questionnaire items, allowing for skip patterns. An analysis will be made of any questionnaire items that register unusually high item nonresponse rates. Multivariate item nonresponse relationships will be evaluated, including monotonicity patterns such as breakoffs (all items dropped after a particular item), and other types of ''blocks'' of multivariate item nonresponse. High levels of item nonresponse in particular items will have their correlations with other questionnaire item results in both the screener and main survey analyzed (tabulating how much the item nonresponse is concentrating in a particular subgroup of health providers).

The FDA anticipates disseminating the results of the study after final analyses of the data are completed, reviewed, and cleared. The information gathered on this topic will be used to inform regulatory guidance to sponsors and investigators designing pregnancy exposure registry protocols.

II. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Gelperin, K., H. Hammad, K. Leishear, et al., ''A Systematic Review of Pregnancy Exposure Registries: Examination of Protocol-Specified Pregnancy Outcomes, Target Sample Size, and Comparator Selection,'' *Pharmacoepidemiology and Drug Safety,* 2017 Feb;26(2):208–214. doi: 10.1002/pds.4150. Epub 2016 Dec 27. PMID: 28028914.
2. FDA, ''Postapproval Pregnancy Safety Studies (May 2019).'' Available at: *https://www.fda.gov/media/124746/download.*
3. National Institutes of Health, Task Force on Research Specific to Pregnant Women

and Lactating Women (PRGLAC). Available at: *https://www.nichd.nih.gov/about/advisory/PRGLAC.*
4. FDA, ''Study Approaches and Methods To Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting,'' May 28–29, 2014. Available at: *https://www.fda.gov/Drugs/NewsEvents/ucm386560.htm.*
5. Daniels, J.L., D.A. Savitz, C. Bradley, et al., ''Attitudes Toward Participation in a Pregnancy and Child Cohort Study,'' *Paediatric and Perinatal Epidemiology,* 2006 May;20(3):260–266. doi: 10.1111/j.1365–3016.2006.00720.x. PMID: 16629701.
6. Hartman, R.I. and A.B. Kimball, ''Performing Research in Pregnancy: Challenges and Perspectives,'' *Clinics in Dermatology,* 2016 May–Jun;34(3):410–415. doi: 10.1016/j.clindermatol.2016.02.014. Epub 2016 Feb 11. PMID: 27265080.
7. Krueger, W.S., M.S. Anthony, C.W. Saltus, et al., ''Evaluating the Safety of Medication Exposures During Pregnancy: A Case Study of Study Designs and Data Sources in Multiple Sclerosis,'' *Drugs Real World Outcomes,* 2017 Sep;4(3):139–149. doi: 10.1007/s40801–017–0114–9. PMID: 28756575; PMCID: PMC5567459.
8. Sarker A., P. Chandrashekar, A. Magge, et al., ''Discovering Cohorts of Pregnant Women From Social Media for Safety Surveillance and Analysis,'' *Journal of Medical internet Research,* 2017 Oct 30;19(10):e361. doi: 10.2196/jmir.8164. PMID: 29084707; PMCID: PMC5684515.
9. Sinclair S., M. Cunnington, J. Messenheimer, et al., ''Advantages and Problems With Pregnancy Registries: Observations and Surprises Throughout the Life of the International Lamotrigine Pregnancy Registry,'' *Pharmacoepidemiology and Drug Safety,* 2014 Aug;23(8):779–786. doi: 10.1002/pds.3659. Epub 2014 Jun 27. PMID: 24974947; PMCID: PMC4406353.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09028 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1402]

Cancer Clinical Trial Eligibility Criteria: Laboratory Values; Draft Guidance for Industry, Institutional Review Boards, and Clinical Investigators; 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, institutional review boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations for selecting appropriate laboratory values as trial eligibility criteria to avoid unjustified exclusions of diverse trial participants.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2024–D–1402 for ''Cancer Clinical Trial Eligibility Criteria: Laboratory Values.'' 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)).