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

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total [2]					12,729

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting and third-party disclosure burden estimates are based on Agency data, which shows that there are six manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Based on this information, we estimate that there are, on average, approximately two infant formula recalls per year.

Thus, we estimate that two respondents conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because we seldom use this section; therefore, we estimate that there are one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on our experience and information from firms that have conducted recalls. We estimate that two respondents will conduct infant formula recalls under § 107.230 and that it takes 4,450 hours to comply with the requirements of that section, for a total of 8,900 hours. We estimate that two respondents conduct infant formula recalls under § 107.240 and that it takes a respondent 1,482 hours to comply with the requirements of that section, for a total of 2,964 hours. We estimate that two respondents submit recommendations for termination of infant formula recalls under § 107.250 and that it takes a respondent 120 hours to comply with the requirements of that section, for a total of 240 hours. Finally, we estimate that one respondent needs to carry out additional effectiveness checks and issue additional notifications, for a total of 625 hours. Therefore, the total annual burden hours for reporting is 12,729 hours (8,900 + 2,964 + 240 + 625).

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
107.230; Elements of infant formula recall	2	1	2	50	100
107.260; Revision of an infant formula recall	1	1	1	25	25
Total					125

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

Table 2 reports FDA's third-party disclosure burden estimates for §§ 107.230 and 107.260. The estimated burden hours per disclosure is an average based on our experience with the information collection. The third-party disclosure burden in § 107.230 is the requirement to promptly notify each affected direct account (customer) about the recall, and if the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post a notice of the recall at the point of purchase. We estimate that two respondents conduct infant formula recalls under § 107.230 and that it takes a respondent 50 hours to comply with the third-party disclosure requirements of that section, for a total of 100 hours. The third-party disclosure burden in § 107.260 is the requirement to issue additional notifications where the recall strategy or implementation is determined to be deficient. We estimate that one respondent issues additional notifications under § 107.260 and that it takes a respondent 25 hours to comply with the third-party disclosure requirements of that section, for a total of 25 hours. The total annual third-party disclosure burden is 125 hours (100 + 25).

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 6, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–17542 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2966]

Male Breast Cancer: 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 ''Male Breast Cancer: Developing Drugs for Treatment.'' This guidance provides recommendations regarding the development and labeling of cancer drugs, including biological products, regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for the treatment of male patients with breast cancer. Specifically, this guidance recommends the inclusion of male patients in clinical trials of breast cancer drugs and provides recommendations on clinical development when males have either not been included in clinical trials for drugs to treat breast cancer or when inclusion of males in those trials is very limited. The development of drugs for male breast cancer may provide clinical data and additional FDA-approved treatment options to improve the clinical management of breast cancer in male patients. The guidance announced in this notice finalizes the draft guidance of the same title issued on August 27, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on August 12, 2020.

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–2019–D–2966 for ''Male Breast Cancer: 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.

- 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, or phone 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, CDER, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, CBER, 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489; 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 guidance for industry entitled ''Male Breast Cancer: Developing Drugs for Treatment.'' This guidance provides recommendations for sponsors regarding the development and labeling of cancer drugs and biological products regulated by CDER and CBER for the treatment of male patients with breast cancer. Males have historically been excluded from clinical trials of breast cancer drugs because breast cancer in males is rare. This has resulted in limited FDA-approved treatment options for males. Clinical management of male breast cancer is generally based on experience with and data from females with breast cancer, rather than on data from prospective, randomized clinical trials.

The final guidance recommends sponsors discuss their breast cancer

drug development plan early in development with CDER or CBER, as applicable. The guidance recommends that eligibility criteria for clinical trials of breast cancer drugs allow for inclusion of males. When males have not been included or when inclusion of males is very limited in clinical trials for breast cancer drugs, the guidance includes clinical development recommendations for when no difference in efficacy or safety is anticipated between males and females based on the drug's mechanism of action and for when there is a concern for differential efficacy or safety between males and females.

This guidance finalizes the draft guidance entitled ''Male Breast Cancer: Developing Drugs for Treatment'' issued on August 27, 2019. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include the addition of examples of topics for early discussion with FDA and expectations regarding nonclinical 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 ''Male Breast Cancer: 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

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *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,* or *https://www.regulations.gov.*

Dated: August 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17575 Filed 8–11–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Health Workforce Connector, OMB No. 0906–0031—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than October 13, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Health Workforce Connector, OMB No. 0906–0031—Extension.

Abstract: More than just a job search portal, the goal of the Health Workforce Connector is to help connect skilled professionals to communities in need by allowing approved Site Points of Contact (POCs), including National Health Service Corps (NHSC) and Nurse Corps, to post available opportunities and update site profiles. The Health Workforce Connector provides a central platform to connect participants, including those in both the NHSC and Nurse Corps programs, and facilities that are approved for performance of their NHSC or Nurse Corps service obligation. The Health Workforce Connector has become a resource that engages any health care professional or student interested in providing primary care services in underserved communities and with facilities in need of health care providers. The Health Workforce Connector also allows users to create a profile, search for NHSC and Nurse Corps sites, find job and training opportunities, search for other clinicians who are similarly interested in working with underserved populations, and be searchable by Site POCs. Individuals can use the Health Workforce Connector's search capability with Google Maps.

Need and Proposed Use of the Information: Information will be collected from users in the following two ways:

(1) *Account Creation:* Creating an account is optional, but to create an account the user will be required to enter their first name, last name, and email address. Those are the only mandatory fields in the profile account creation process and will be used to send an automated email allowing the user to validate their login credentials. This information will also be used to validate any users who already exist within the Bureau of Health Workforce Management Information Systems Solution (BMISS) database and allow an initial import of existing data at the request of the user.

(2) *Profile Completion:* Users may fill out a profile, but this function will be completely optional and will include fields such as location, discipline, specialty, and languages spoken. The information collected, if 'published' by the user, will allow internal BMISS Site POCs to search for anyone who may be a potential candidate for job opportunities at the site. Users also have the ability to make their profiles searchable by other end users through a security and privacy setting and can make their profiles private at any time. All information collected will be stored within existing secure BMISS databases and will be used internally for report generation on an as-needed basis.

Likely Respondents: Potential users will include individuals searching for a health care job opportunity or an NHSC or Nurse Corps health care facility, and