TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Time and extent application and submission of information (§ 330.14(c) and (d))	2	1	2	1,525	3,050
Safety and effectiveness data (§ 330.14(f) and (i))	2	1	2	2,350	4,700
Sponsor request for an informal conference (§ 330.14(j)(3))	1	1	1	1	1
Sponsor signed statement that submission is complete (§ 330.14(j)(4))	2	1	2	1	2
Sponsor request for FDA to withdraw TEA consideration (§ 330.14(k)(1))	1	1	1	1	1
Sponsor request for FDA not to deem the submission withdrawn (§ 330.14(k)(2))	1	1	1	2	2
Total					7,756

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

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: July 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16528 Filed 7–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1551]

Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is intended to assist applicants in complying with the content and format requirements of the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling for human prescription drug and biological products. This draft guidance revises the draft guidance issued in December 2014. This revision provides clarification and additional information on recommendations to applicants submitting new drug applications (NDAs), biologics license applications (BLAs) (for biological products that are regulated as drugs), and efficacy supplements to approved NDAs or BLAs.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2014–D–1551 for ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft 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 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6469, Silver Spring, MD 20993–0002, 301–796–6169; 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 draft guidance for industry entitled ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The final rule, *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling,* referred to as the PLLR, which published December 4, 2014 (79 FR 72063), modified the labeling requirements for human prescription drug and biological products. The PLLR amended FDA's regulations governing the content and format of the ''Pregnancy,'' ''Labor and Delivery,'' and ''Nursing Mothers'' subsections of the ''Use in Specific Populations'' section of the existing labeling for human prescription drug and biological products. This guidance is intended to assist applicants in complying with the content and format requirements of the ''Pregnancy,'' ''Lactation,'' and ''Females and Males of Reproductive Potential'' subsections of labeling for human prescription drug and biological products, as described in the PLLR. This draft guidance revises the draft guidance of the same name issued December 4, 2014 (79 FR 72104). The revisions provide clarification and additional information on recommendations in response to public comments and the Agency's regulatory experience implementing the PLLR. Changes to this draft guidance from the previous draft guidance include the addition of the following:

- Information on formatting, omitting information, and pregnancy registries.
- Clarifying information related to the Risk Summary heading, risk statements, and human and animal data.
- Information on labeling for section 8.3 Females and Males of Reproductive Potential, including information on pregnancy testing, contraception, and infertility.
- Procedural information on implementation and submission of draft labeling to the Agency for review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format.'' 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

FDA tentatively concludes that this draft guidance contains no collection 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.

However, this draft guidance refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collection of information in 21 CFR 201.56 and 201.57 for preparing and submitting labeling has been approved under OMB control number 0910–0572. The collections of information in 21 CFR 314.70 and 314.97 for submitting supplements to an approved application, in 21 CFR 314.50(e) for submitting labeling for an application, and in 21 CFR 314.90 for submitting waiver requests for an application have been approved under OMB control number 0910–0001. The collection of information in 21 CFR 601.12 for submitting supplements to an approved application has been approved under OMB control number 0910–0338. In addition, the information collection provisions of the PLLR have been approved under OMB control number 0910–0624.

III. Electronic Access

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

Dated: July 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16530 Filed 7–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID–19 Hoarding Prevention Measures Under Executive Order 13910 and Section 102 of the Defense Production Act of 1950

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the extension of the designation issued March 25, 2020 under Executive Order 13910 (Executive Order) and section 102 of the Defense Production Act of 1950 (the Act), 50 U.S.C. 4512,