20852, 301–796–7726, *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.

Assessment of Combination Product Review Practices

OMB Control Number 0910–NEW

In 1991, FDA's Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health entered into ''Intercenter Agreements'' to provide guidance on the classification and assignment of medical products and to clarify jurisdiction over combination product reviews. With the enactment of the Medical Device User Fee and Modernization Act of 2002, FDA aimed to achieve prompt assignment of combination products, timely and effective premarket reviews, and consistent and appropriate postmarket regulation through the establishment of the Office of Combination Products (OCP). Since then, OCP has operated to further standardize combination product guidance to FDA and industry and facilitate coordination between FDA's medical product review Centers. As part of the 2017 reauthorization of the Prescription Drug User Fee Act (PDUFA), FDA committed to advance the development of drug-device and biologic-device combination products regulated by CDER and CBER through modernization of the combination product review program. To that end, FDA committed to contracting with an independent third party to assess current practices for combination drug product review, to include interviews with combination product sponsors and applicants. The contractor for the assessment of combination drug product review practices is Eastern Research Group, Inc. (ERG).

Therefore, in accordance with the PDUFA VI Commitment Letter, FDA proposes to have ERG conduct independent interviews of combination product sponsors and applicants during the data collection period as follows:

- Sponsors with a Request For Designation (RFD) or pre-RFD submitted during the data collection period.
- Sponsors with a combination product Investigational New Drug (IND) or pre-IND submitted during the data collection period.
- Applicants with a combination product New Drug Application (NDA) or Biologics License Application (BLA) that receives a first-cycle action from FDA during the data collection period.

The purpose of these interviews is to collect voluntary feedback from combination product sponsors and applicants on their experience with FDA during the development and review of their products, including any challenges or best practices. ERG will anonymize and aggregate sponsor/applicant responses prior to inclusion in the assessment. ERG will use interview responses to complement and supplement data on combination product review parameters obtained through other means, such as extraction of data from FDA corporate databases and interviews with FDA review staff. FDA will publish ERG's assessment (with interview results and findings) on the Agency's public website and a link to the assessment in the **Federal Register** for public comment.

In the **Federal Register** of September 27, 2018 (83 FR 48822), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Sponsors submit approximately 150 to 180 RFDs/pre-RFDs and 200 to 240 combination product original INDs/pre-INDs per year. ERG will interview 1 to 3 sponsor representatives at a time for up to 35 RFDs/pre-RFDs and 48 INDs received by FDA—up to 105 RFD/pre-RFD and 144 IND/pre-IND sponsor representatives per year. FDA typically reviews approximately 25 to 30 combination product original NDAs and original BLAs per year. ERG will interview 1 to 3 applicant representatives at a time for each application that receives a first-cycle action from FDA—up to 90 representatives per year. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Pretest	5	1	5	1.5	7.5
Interviews	339	1	339	1.5	508.5
Total					516

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

ERG will conduct a pretest of the interview protocol with five respondents. FDA estimates that it will take 1 to 1.5 hours to complete the pretest, for a total of a maximum of 7.5 hours. FDA estimates that up to 339 respondents will take part in the interviews each year, with each interview lasting 1 to 1.5 hours, for a total of a maximum of 508.5 hours. Thus, the total estimated annual burden is 516 hours. FDA's burden estimate is based on prior experience with similar interviews with the regulated community.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01979 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4735]

Agency Information Collection Activities; Proposed Collection; Comment Request; Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

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, 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 safety labeling changes and the implementation of a certain section of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by April 15, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 15, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 15, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2018–N–4735 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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, including each proposed extension of an existing 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.

Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0734—Extension

Section 505(o)(4) of the FD&C Act (21 U.S.C. 355(o)(4)) authorizes FDA to require and, if necessary, order labeling changes if FDA becomes aware of new safety information that it believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) imposes time frames for application holders to submit, and FDA staff to review, such changes and gives FDA enforcement tools to bring about timely and appropriate labeling changes. To implement these provisions we developed the guidance entitled ''Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act,'' which provides instruction on: (1) A description of the types of safety labeling changes that ordinarily might be required; (2) how FDA plans to determine what constitutes new safety information; (3) the procedures involved in requiring safety labeling changes, and (4) enforcement of the requirements for safety labeling changes. The guidance is available on our website at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm250783.pdf.*

FDA requires safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B) of the FD&C Act, the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and by submitting a statement detailing why the application holder does not believe a change is warranted (a rebuttal statement).

Based on our experience to date with safety labeling changes requirements under section 505(o)(4) of the FD&C Act, we estimate that approximately 36 application holders will elect to submit approximately 1 rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, the guidance explains that labeling prepared in response to a safety labeling change notification should be available on the application holder's website within 10 calendar days of approval. We estimate that approximately 351 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

We estimate the burden of the information collection 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
Rebuttal statement	36	1	36	6	216

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

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

Type of submission	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Posting approved labeling on application holder's website	351	1	351	4	1,404

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

We have adjusted our estimated annual number of respondents downward by 62 since the last OMB approval of the information collection. The decrease reflects that we have issued fewer safety labeling notifications, and thus fewer postings are required and fewer rebuttals are expected.

Dated: February 6, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–01918 Filed 2–11–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by March 14, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0014. Also include the FDA docket number found