



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2969]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Assessment of Combination Product Review Practices

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Assessment of Combination Product Review Practices.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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 Burden¹

Portion of Study	No. of Respondents	No. 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.

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