4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-0040]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry; How to Prepare a Pre-Request for Designation

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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry; How to Prepare a Pre-Request for Designation (Pre-RFD)." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, 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.

Draft Guidance for Industry; How to Prepare a Pre-Request for Designation (Pre-RFD)

OMB Control Number 0910-NEW

Since its establishment on December 24, 2002, the FDA Office of Combination Products (OCP) has served as a resource for sponsors at various stages of development of their product. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biologic, or a combination product, and which FDA medical product Agency Center (Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, or Center for Devices and Radiological Health) will regulate it, if it is a non-combination product, or will have the primary jurisdiction for the premarket review and regulation of the product, if it is a combination product.

There are two ways that a sponsor can receive such feedback from OCP. One option is to submit an RFD to receive a formal, binding determination for the sponsor's product with respect to classification and/or center assignment that may be changed under conditions specified in section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-2) and 21 CFR 3.9 in the regulations. The RFD process is codified in 21 CFR part 3, and OCP has issued a guidance about this process (see "How to Write a Request for Designation" at https://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm). A second more

flexible option is for a sponsor to submit an inquiry to OCP to receive a preliminary jurisdictional assessment, which is not binding.

Many sponsors seek to utilize the flexibility of more approachable ways to interact with OCP and the medical product Agency Centers to obtain feedback from the Agency before submitting a marketing application to the Agency. Over time, these informal methods of obtaining feedback have become increasingly customary with sponsors, and for some, even preferable to the formal RFD process. Accordingly, FDA is enhancing the transparency and consistency of this process, which will now be called the "Pre-Request for Designation (Pre-RFD) Program."

This draft guidance describes this structured process with clear recommendations for sponsors wishing to submit Pre-RFDs. It also provides the process for review of Pre-RFDs by FDA staff, the general timeframes for sponsors to receive feedback from OCP, and the process for scheduling teleconferences and meetings in relation to a Pre-RFD.

This draft guidance describes how to prepare a Pre-RFD. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between OCP, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

In the *Federal Register* of January 13, 2017 (82 FR 4351), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited and therefore will not be discussed.

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
Pre-RFD Submissions	136	1	136	12	1,632
Pre-RFD Meetings	136	1	136	1	136
Total					1,768

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

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-15005 Filed: 7/17/2017 8:45 am; Publication Date: 7/18/2017]