4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1339]

Pilot Program for Request for Designation and Pre-Request for Designation Electronic Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Office of Combination Products (OCP) in the Food and Drug Administration (FDA) is soliciting applications from members of the public interested in participating in a voluntary pilot program to help OCP evaluate a potential new electronic submissions process for Requests for Designation (RFD) and Pre-RFD. This RFD and Pre-RFD electronic submission process is intended to improve efficiency and completeness of RFD and Pre-RFD submissions. OCP plans to accept up to nine participants for the pilot program. The pilot program is intended to provide OCP input to inform this evaluation.

DATES: Interested parties should submit an electronic application to participate in this pilot program by [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. We plan to conduct pilot testing beginning on or about [INSERT DATE 21 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section III of this document for information on applying for participation.

FOR FURTHER INFORMATION CONTACT: Danita Dixon, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2889, danita.dixon@fda.hhs.gov.

ADDRESSES: If you are interested in participating in this pilot program, please submit an electronic application to combination@fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment on December 24, 2002, OCP has served as a resource for sponsors at various stages of development of their products. Sponsors often seek OCP feedback on whether their medical product will be regulated as a drug, a device, a biological product, or a combination product, and which medical product FDA Center (Center for Devices and Radiological Health, Center for Drug Evaluation and Research, or Center for Biologics Evaluation and Research) 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. 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 (RFD)" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd). A second option referred to as the Pre-RFD submission process, is for a sponsor to submit an inquiry to OCP to receive a preliminary assessment of their product's classification and/or assignment, which is not binding. The Pre-RFD process allows for more flexible interaction between sponsors and FDA. RFD and Pre-RFD submissions to OCP are currently, typically submitted via email, although some are submitted in paper copies. Regardless of format, some submissions lack sufficient data for review. Consequently, OCP is

announcing a pilot program to test the functionality of a more structured RFD and Pre-RFD electronic submission process that should enhance efficiency and ensure sponsors' understanding of required and recommended submission content.

II. Pilot Program Participation

The pilot program to evaluate the RFD and Pre-RFD electronic submission processes is to last approximately 2 weeks. During the pilot program, OCP staff will be available to address questions or concerns that may arise. Pilot program participants will receive training and will be asked to submit simulated regulatory submissions using data provided to them by OCP for testing purposes. Pilot program participants will also be asked to provide written and verbal feedback during their training and after they submit the simulated regulatory submissions. This feedback will assist OCP in developing the electronic submission processes. OCP estimates that each individual participant's involvement may require about 15 hours over the 2-week period. OCP is soliciting applications from members of the public, such as combination product and other medical product sponsors, as well as entities that may act as authorized agents submitting RFDs or Pre-RFDs for sponsors. At its discretion, OCP may withdraw a participant from the pilot program for not completing the requested activities within requested timeframes.

III. Applications for Participation

Send applications to participate in the pilot program to combination@fda.gov. Applications should include the following information: company and contact name, contact phone number, and contact email address. Additionally, although not required for consideration, OCP is particularly interested in whether you are a sponsor or may act as an authorized agent, and whether you have previously submitted an RFD or Pre-RFD. Once applications for participation are received, FDA will contact interested applicants to confirm selection for the

pilot program. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot program.

Dated: July 30, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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