4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Externally-Led Patient-Focused Drug Development Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the opportunity for externally-led patient-focused drug development meetings. The Patient-Focused Drug Development (PFDD) initiative is part of FDA's commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The PFDD initiative aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA recognizes that there are many more disease areas than can be addressed in the planned FDA meetings under PDUFA V. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through Patient-Focused Drug Development as a model.

ADDRESSES: FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting initially engage with FDA by submitting a letter of intent (LOI) to patientfocused@fda.hhs.gov. Submission details are outlined on FDA's Web site: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and

Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1144, Silver Spring, MD 20993-0002, 301-796-0684.

SUPPLEMENTARY INFORMATION: As part of its commitments under the Prescription Drug User Fee Act reauthorization of 2012, FDA has taken several steps to inform the benefit-risk assessments that inform CDER's regulatory decisions concerning new drugs. Among these efforts is the PFDD initiative that aims to more systematically obtain the patient perspective on specific diseases and their treatments. FDA has committed to obtaining the patient perspective on at least 20 disease areas during the course of PDUFA V. PFDD meetings give FDA an important opportunity to hear directly from patients, patient advocates, and caretakers about the symptoms that matter most to them; the impact the disease has on patients' daily lives; and patients' experiences with currently available treatments. The patient perspective is critical in helping FDA understand the context in which regulatory decisions are made for new drugs. This patient input can inform FDA's decisions and oversight both during drug development and during our review of a marketing application.

The Agency recognizes that there has been growing external interest in expanding efforts to gather patient input in support of drug development and evaluation. To help expand the benefits of FDA's PFDD initiative, FDA welcomes patient organizations to identify and organize patient-focused collaborations to generate public input on other disease areas, using the process established through Patient-Focused Drug Development as a model. An externally-led PFDD meeting and any resulting products (e.g., surveys or reports) will not be considered FDA-sponsored or FDA-endorsed, and FDA does not guarantee specific involvement in such meetings. However, FDA will be open to participating in a well-designed and well-conducted

meeting on a case-by-case basis. Given the expanse of diseases affecting the U.S. patient population and the effort required to conduct a successful PFDD meeting, externally-led PFDD meetings should target disease areas where there is an identified need for patient input on topics related to drug development. FDA will determine its level of participation in these meetings on an individual basis, taking into account a number of factors, including any identified need for a better understanding of patient perspective, recent interactions with patient stakeholders, proposed meeting details, and FDA staff capacity. More information regarding considerations to take into account when deciding to plan an externally-led PFDD meeting can be found on this Web site: http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm453856.htm.

FDA recommends that patient organizations who are interested in conducting an externally-led PFDD meeting submit an LOI that communicates (1) the value of the proposed meeting in the context of drug development for a particular disease area, and (2) important details regarding the meeting plan. Guidelines for developing a letter of intent are provided here: http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM453857.pdf. Please submit the letter of intent to patientfocused@fda.hhs.gov. FDA's CDER Office of Strategic Programs will receive and review the letter.

Dated: December 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-32476 Filed: 12/24/2015 8:45 am; Publication Date: 12/28/2015]