4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Over-the-Counter Monograph User Fees: Stakeholder Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an Over-the-Counter (OTC) Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

DATES: FDA will hold a webinar for stakeholders on Wednesday, August 23, 2017, from 12:30 p.m. to 2 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Mary Vienna , Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-4150, email: *OTCMonographUserFeeProgram@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

On June 10, 2016, FDA held a public meeting on a potential new user fee program for nonprescription (over-the-counter or OTC) monograph drugs. In the announcement of the public

meeting in the Federal Register (May 11, 2016, 81 FR 29275), FDA invited public comment as the Agency considers a user-fee program for OTC monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. Interested persons were given until July 11, 2016, to submit comments. A stakeholder webinar was held on September 6, 2016, which provided stakeholders with a status update on the process of FDA and industry discussions that began in July 2016. In the notice of public meeting (August 8, 2016, 81 FR 52444), FDA invited public comments and interested parties were given until October 6, 2016, to submit comments.

FDA will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an OTC Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

II. Background

Meeting minutes from FDA and industry discussions on a new OTC monograph user fee program can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm* . The proposed OTC Monograph User Fee Program Performance Goals and Procedures – Fiscal Years 2018-2022 document can also be found at that same website.

Additional background information on OTC monograph drugs (such as how OTC drugs can be marketed, and the differences between marketing through approved applications and marketing under the monographs), factors FDA considers important in developing a user-fee program, and the questions for which FDA asked the public to consider and provide input, can be found in the Federal Register notice from the June 10, 2016, public meeting (*https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments*). The meeting transcript, meeting recording, and

presentations from the June 10, 2016, public meeting, which can serve as further background information, can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm* . A summary of the September 6, 2016, stakeholders' webinar, can also be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm* .

III. Stakeholder Meeting Participation

FDA is seeking participation at the webinar by stakeholders, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. Participating in the webinar is free. The webinar format will include presentations by FDA staff and an opportunity for stakeholders to ask questions. If you wish to attend the webinar, FDA asks that you please register through Eventbrite by 12 a.m. EDT, Saturday, August 19, 2017: *https://www.eventbrite.com/e/over-the-counter-monograph-user-fees-stakeholder-meeting-registration-33593404778* . FDA will email the registered attendees a URL to join the webinar at least 1 day before the meeting.

Dated July 27, 2017.

Anna K. Abram,

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

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