4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0802]

Exploring Naloxone Uptake and Use; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research, in collaboration with the National Institutes on Drug Abuse, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration, will hold a public meeting to discuss increasing the use of naloxone to reduce the incidence of opioid drug overdose fatalities. During the meeting, academic and government experts, industry representatives, and patient advocates will discuss which populations are at-risk for opioid drug overdose and how we can work together to encourage the use of naloxone to reduce the risk of overdose from opioid drugs.

Date and Time: The public meeting will be held on July 1, 2015, from 8 a.m. to 5 p.m. and on July 2, 2015, from 8 a.m. to 3 p.m. The open public hearing will be held between 1 p.m. and 2 p.m. on July 1, 2015, and between 1 p.m. and 2 p.m. on July 2, 2015, during which speaker testimony will be accepted. We will try to accommodate all persons who wish to testify; however, the duration of each speaker's testimony may be limited by time constraints. Those wishing to participate in the open public hearing should limit their remarks to issues related to

the uptake of naloxone both in conventional medical settings and outside of those settings to reduce the incidence of opioid drug overdose fatalities.

Location: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002.

Contact Person: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD20993-0002, 301-796-3519, Mary.Gross@fda.hhs.gov; or Georgiann Ienzi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3515, Georgiann.Ienzi@fda.hhs.gov.

Registration: If you wish to attend the public meeting or provide testimony during the open public hearing, please email your registration to NaloxoneWorkshop@fda.hhs.gov by June 22, 2015. Those without email access may register by contacting one of the contact persons (see Contact Persons). When registering, please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted for the public meeting. Onsite registration on the day of the public meeting will be permitted based on space availability. If registration reaches maximum capacity, FDA will post a notice closing registration for the public meeting at: http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm.

Comments: Submit either electronic or written comments by September 1, 2015. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of

Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm.1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. If you need special accommodations due to a disability, contact Mary Gross or Georgiann Ienzi (see Contact Persons) at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Introduction

The number of prescriptions filled for opioid drugs has increased drastically in recent years. In 2009 nearly 257 million prescriptions were written for opioid drugs in the United States. This number rose to nearly 260 million in 2012. The increased availability of opioid drugs appears to be contributing significantly to abuse and overdose in the United States. In 2013 there were approximately 16,235 deaths from overdose involving opioid drugs. That same year, there were 8,257 deaths from overdose involving heroin.

Naloxone, a mu-opioid antagonist, is a medication that can rapidly reverse the overdose of both prescription opioid drugs (e.g., OxyContin) and illicit opioid drugs (e.g., heroin). It is currently the standard treatment for those experiencing overdose and is commonly used by trained medical personnel in emergency departments and on ambulances. Its use among nonmedical personnel has also increased in recent years. The purpose of the public meeting is to explore issues surrounding the uptake of naloxone to treat opioid drug overdose. The meeting agenda will include topics on the clinical, regulatory, and legal implications of making naloxone more widely available. FDA will post the agenda and additional public meeting material

approximately 2 days before the workshop at:

http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm.

II. Transcripts

A transcript will be made available approximately 45 days after the public meeting. It will be accessible at http://www.regulations.gov and may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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