Dated: November 9, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0802]

Role of Naloxone in Opioid Overdose Fatality Prevention; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in collaboration with the Office of the Assistant Secretary for Health, National Institutes of Drug Abuse, and the Centers for Disease Control and Prevention, is announcing a scientific workshop to initiate a public discussion about the potential value of making naloxone more widely available outside of conventional medical settings to reduce the incidence of opioid overdose fatalities. Academia, government, industry experts, and patient advocates will be assembled to discuss which populations are at risk for opioid overdose and how public health groups are working together to curb the abuse of opioids. We will also seek to identify potential health concerns, social concerns, legal concerns, regulatory issues, and future research needs related to making naloxone more widely available.

Date and Time: The public workshop will be held on April 12, 2012, from 8:30 a.m. to 5:30 p.m.

Location: The public workshop will be held at 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, MD 20993–0002, (301) 796–3519, *Mary.Gross@fda.hhs.gov;* or Matthew Petcovic, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, (301) 796–5242, *Matthew.Petcovik@fda.hhs.gov.*

Registration: If you wish to attend the public workshop or provide testimony during the open public hearing, please email your registration to *CDER_Naloxone_Workshop@fda.hhs.gov* by March 28, 2012. Those without email access may register by contacting one of the persons listed in the *Contact Person* section of this document. 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 workshop. Onsite registration on the day of the public workshop will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm277119.htm.*

An open public hearing will be held between 2:45 p.m. and 3:45 p.m. on April 12, 2012, 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 during this open public hearing may be limited by time constraints. Those wishing to participate in the open public hearing should limit their remarks to a discussion of the advantages and/or disadvantages to making naloxone more easily accessible to patients outside of conventional medical settings.

Comments: Submit either electronic or written comments by June 12, 2012. 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 necessary to send only 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.

If you need special accommodations due to a disability, contact Mary Gross or Matt Petcovic (see *Contact Person*) at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

I. Introduction

The number of prescriptions filled for opioid pain relievers has increased dramatically in recent years. Nearly 257 million prescriptions for opioid drugs were written in the United States in 2009 alone and the increased availability to prescription opioid drugs appear to be contributing significantly to abuse and the potential for overdose in the United States. In the United States, mortality rates closely correlate with opioid sales. In 2007, approximately 36,034 people died from unintentional overdoses. At least 14,459 of these deaths involved prescription opioid analgesics. Moreover, according to the Substance Abuse and Mental Health Services Administration, the number of Americans in 2009 aged 12 and older currently abusing pain relievers has increased by 20 percent since 2002. Naloxone, a mu-opioid antagonist, is an injectable medicine that can rapidly reverse the overdose of either prescription (*e.g.,* OxyContin) or illicit (*e.g.,* heroin) opioids. It is currently the standard treatment for those who overdose on opioid drugs, but is most commonly used only by trained medical personnel in emergency departments and on ambulances. The purpose of this public workshop is to discuss the issues around making naloxone more widely available. This includes work to expand its use through the development of novel formulations as well as work to potentially support its use by individuals other than the trained medical personnel currently authorized to use it.

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: *http://www.fda.gov/Drugs/NewsEvents/ucm277119.htm.*

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be made available. 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: November 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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