4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0067]

Assessment of Analgesic Treatment of Chronic Pain--A Public Workshop; Request for Comments

AGENCY: Food and Drug Administration.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a public workshop to hear a discussion of the available data on the efficacy of analgesics in the treatment of chronic non-cancer pain (CNCP). The focus of the presentations and discussions by scientific experts and other stakeholder groups will be on the available clinical data from both randomized clinical trials and other studies of the efficacy of opioid analgesics, and comparison of that data to the data from studies of non-opioid analgesics used in the treatment of CNCP.

Date and Time: The public workshop will be held on May 30, 2012, from 1 p.m. to 5:15 p.m. and on May 31, 2012, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Natcher Auditorium, Natcher Conference Center, National Institutes of Health Campus, 45 Center Dr., Bethesda, MD 20892

Contacts: Mary C. Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6178, Silver Spring, MD 20993-0002, 301-796-3519; or Matthew Sullivan, Center for Drug Evaluation, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3160, Silver Spring, MD 20993-0002, 301-796-1245.

Registration: If you wish to attend the workshop or provide oral comments during the open session of the meeting, please email your registration to CDER_ChronicPain_Workshop @FDA.HHS.GOV by May 15, 2012. Those without email access may register by contacting one of the persons listed in the Contacts section of the 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. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing the meeting registration for the workshop at: http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm.

An open session of the meeting will be held between 3:45 p.m. and 5 p.m. on May 30, 2012, during which time public comments will be accepted. We will try to accommodate all persons who wish to speak at this open session, however, the duration of each speaker's testimony may be limited by time constraints.

Comments: Submit either electronic or written comments by August 1, 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 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.

If you need special accommodations due to a disability, contact Mary Gross or Matthew Sullivan (see Contacts) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Introduction

CNCP is a major cause of pain and disability for millions of Americans. The prescribing of opioids for pain has risen steadily in the United States over the past two decades, including the prescribing of opioids to treat CNCP. Questions have been raised about the efficacy of opioids in the treatment of CNCP, including which patients benefit from the chronic use of opioids, the durability of analgesia provided by opioid analgesics, and how best to manage the use of these drugs. Addressing this uncertainty begins with a discussion of the available scientific data on the use of opioids in chronic painful conditions. The discussion will include health care professionals, clinical investigators, regulators, manufacturers, patients, caregivers, and advocacy groups. Where gaps in our knowledge are identified, it will be important to discuss the research that needs to be undertaken to better understand the effectiveness of all analgesics for the treatment of chronic non-cancer pain, and opioid analgesics in particular.

The purpose of the meeting is to provide a forum to discuss the available data on the use of analgesics in the treatment of CNCP, beginning with a discussion of the underlying mechanisms of chronic pain and the epidemiology of chronic pain in the United States. Next, data on the efficacy of opioids and other analgesics in the treatment of chronic pain from a variety of sources will be reviewed. Those sources will include randomized controlled trials, epidemiological studies, case series and other types of studies. Patient and clinician perspectives on the pharmaceutical treatment of CNCP will be presented by people living with chronic pain and those who treat or care for patients with chronic pain. Finally, a general assessment of the available data and discussion of future research needs and next steps will be used to inform future actions that can help guide appropriate therapy for patients with CNCP.

FDA will be considering the following questions during the workshop:

1. What is currently known about the mechanisms of chronic pain?

2. How might this knowledge affect the use of pharmaceuticals chronically for the treatment of pain?

3. What is known regarding use of pain biomarkers (e.g., phenotyping, imaging, genotyping)?

4. What is known about the sources of chronic pain, the populations affected by it, and trends in current use of pharmaceuticals in its treatment?

5. What data are available from controlled trials that have examined the use of pharmaceuticals in the treatment of chronic pain?

6. What data are available from other sources on the use of pharmaceuticals in the treatment of chronic pain?

7. Can populations and individuals who would benefit from chronic use of pharmaceuticals be identified?

8. Can individuals at high risk for adverse effects be identified?

9. What more should be known about the use of pharmaceuticals to treat chronic pain?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at http://www.fda.gov/Drugs/NewsEvents/ucm283979.htm.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be 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: February 2, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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