4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0045]

Abuse-Deterrent Opioids--Evaluation and Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Abuse-Deterrent Opioids--Evaluation and Labeling". This guidance explains FDA's current thinking about the studies that should be conducted to demonstrate that a given formulation has abuse-deterrent properties. This guidance also makes recommendations about how those studies should be performed and evaluated, and discusses how to describe those studies and their implications in product labeling. It is intended to assist sponsors who wish to develop opioid drug products with potentially abuse-deterrent properties and is not intended to apply to products that are not opioids or opioid products that do not have the potential for abuse.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002.

Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

FOR FURTHER INFORMATION CONTACT: Brutrinia D. Cain, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4633, Brutrinia.Cain@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Abuse-Deterrent Opioids--Evaluation and Labeling." Prescription opioid products are an important component of modern pain management. However, abuse and misuse of these products have created a serious and growing public health problem. One potentially important step towards the goal of creating safer opioid analgesics has been the development of opioids that are formulated with some properties intended to deter abuse. FDA considers development of these products a high public health priority.

The guidance is intended to provide industry with a framework for evaluating and labeling abuse-deterrent opioid products. The guidance discusses how the potentially abuse-deterrent properties of an opioid analgesic formulated to deter abuse should be studied, specifically addressing in vitro studies, pharmacokinetic studies, clinical abuse potential studies, and postmarket studies. The guidance also describes the types of information that may be suitable for inclusion in labeling.

Providing a clear framework for the evaluation and labeling of the abuse-deterrent properties of opioid analgesics intended to deter abuse should help to incentivize the development of safer, less abusable opioid analgesics, and should also facilitate the dissemination of fair and accurate information regarding such products.

In the Federal Register of January 14, 2013 (78 FR 2676), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance. The Agency has made revisions to the guidance as it deemed appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the evaluation and labeling of abuse-deterrent opioids. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: March 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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