4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2300]

Evaluating Drug Effects on the Ability to Operate a Motor Vehicle; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Evaluating Drug Effects on the Ability to Operate a Motor Vehicle." The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle. Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities. Reducing the incidence of motor vehicle accidents (MVAs) that occur because of drug-impaired driving is a public health priority. This draft guidance recommends using a systematic effort to identify drugs that increase the risk of MVAs as a critical component of assessing drug risk and designing strategies to reduce this risk.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on

the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Aaron Sherman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4339, Silver Spring, MD 20993-0002, 240-402-0493.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Evaluating Drug Effects on the Ability to Operate a Motor Vehicle." The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle.

Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities that can be adversely affected by therapeutic drugs. Reducing the incidence of MVAs that occur because of drug-impaired driving is a public health priority.[1]

Drugs that impair driving ability may also impair the ability to judge the extent of one's own impairment. This increases the need for objective evaluation of the presence and degree of driving impairment, with risk mitigation strategies based on that information. This guidance recommends a systematic effort to identify drugs for which evaluation of effects on driving abilities may be needed, and the types of studies that such an evaluation entails.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on evaluating drug effects on the ability to operate a motor vehicle. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have

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[1] See the Drugged Driving Web page on the Office of National Drug Control Policy Web site at http://www.whitehouse.gov/ondcp/drugged-driving.

been approved under OMB control numbers 0910-0014 and 0910-0001, respectively. The collection of information for prescription drug product labeling is approved under OMB control number 0910-0572.

III. 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.

IV. 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: January 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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