

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Medication Guides—Distribution Requirements and Inclusion of Medication Guides in Risk Evaluation and Mitigation Strategies (REMS)." This draft guidance is intended to address two topics pertaining to Medication Guides for drug and biological products.

Medication Guides are primarily for prescription drug and biological products used on an outpatient basis without direct supervision by a healthcare professional. Questions have arisen concerning when a Medication Guide must be distributed with a drug or biological product dispensed to a healthcare professional for administration to a patient in certain situations, for example, in an inpatient setting or an outpatient setting such as a clinic or infusion center. This draft guidance is intended to articulate the circumstances under which FDA intends to exercise enforcement discretion regarding Medication Guide distribution.

The second topic addressed by the draft guidance is when a Medication Guide will be required as part of a REMS. Under section 505-1(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355-1(e)), FDA may require that a REMS for a drug include one or more of the elements described in section 505-1(e), including (when the criteria in part 208 (21 CFR part 208) are met), the requirement for an applicant to develop a Medication Guide for distribution to each patient when the drug is dispensed. Since the enactment of the Food and Drug Administration Amendments Act of 2007, FDA has, as a matter of policy, considered any new Medication Guide (or safety-related changes to an existing Medication Guide) to be part of a REMS. However, the Agency has the authority to determine, based on the risks of a drug and public health concern, how a Medication Guide should be required

when the standard in part 208 is met. Based on the risks and public health concern, the Agency may require:

(1) A Medication Guide in accordance with part 208 that is not a part of a REMS or

(2) A Medication Guide in accordance with part 208 and section 505-1 of the FD&C Act that is part of a REMS, which will include other parts of a REMS (such as the timetable for submission of assessments) and possibly other REMS elements (including elements to assure safe use).

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 when FDA intends to exercise enforcement discretion regarding Medication Guide distribution and inclusion of Medication Guides in REMS. 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. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 §§ 314.70 and 600.12 have been approved under OMB control numbers 0910-0001 and 0910-0338; the collections of information in part 208 have been approved under OMB control number 0910-0393.

IV. Electronic Access

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

BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or <http://www.regulations.gov>.

Dated: February 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: March 15, 2011.

Time: 11 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Ken D. Nakamura, PhD, Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4076, MSC 9306, Rockville, MD 20852. 301-402-0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS).

Dated: February 18, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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