

- To assess signals of serious risk related to the use of the drug; or
- To identify an unexpected serious risk when available data indicates the potential for a serious risk.

This guidance provides information on the implementation of new section 505(o)(3) of the FD&C Act. The guidance also describes which types of postmarketing studies and clinical trials will be required (PMRs) under section 505(o)(3) and which types will be agreed-upon commitments because they do not meet the statutory criteria for required studies and trials (PMCs).

In the **Federal Register** of July 15, 2009 (74 FR 34358), FDA announced the availability of a draft guidance for industry entitled "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act." The notice gave interested persons the opportunity to comment by October 13, 2009. The draft guidance was revised in response to comments submitted to the docket requesting that the guidance clearly distinguish PMRs required under section 505(o)(3) of the FD&C Act from risk evaluation and mitigation strategies. The revisions also provide additional detail in the examples of PMRs and PMCs and clarify reporting requirements.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the implementation of section 901 of FDAAA on postmarketing studies and clinical trials. 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 guidance provides information on the implementation of section 901 of FDAAA. The collections of information requested in the draft guidance would

be submitted under 21 CFR 314.80, 314.81, and 601.70. 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) and are approved under OMB control numbers 0910–0230, 0910–0001, and 0910–0338. Section VI of the guidance refers to procedures in the guidance entitled "Formal Dispute Resolution: Appeals Above the Division Level," which contains collections of information approved under OMB control number 0910–0430.

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

Dated: March 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0066]

Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee; Notice of Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until May 2, 2011, the comment period for the notice announcing a meeting of the Molecular and Clinical Genetics Panel (the panel) of the Medical Devices Advisory Committee that published in the **Federal Register** of February 7, 2011 (76 FR 6623). In the notice, FDA requested public comment regarding the March 8 and 9, 2011, meeting of the panel to discuss and make recommendations on scientific issues concerning direct to consumer (DTC) genetic tests that make medical claims. FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments and information by May 2, 2011.

ADDRESSES: Submit electronic comments or information 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Mansfield, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, rm. 5676, Silver Spring, MD 20993–0002, 301–796–4664.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 7, 2011 (76 FR 6623), FDA published a notice announcing a meeting of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee, and the opening of a public docket to seek input and comments from interested stakeholders to discuss scientific issues concerning DTC tests. Interested persons were given until March 1, 2011, to submit comments.

II. Request for Comments

Following publication of the February 7, 2011, notice, FDA received requests to allow interested persons additional time to comment. The requesters asserted that the initial time period was insufficient to allow potential respondents to thoroughly evaluate and assess pertinent issues. The Agency has considered the requests and is reopening the comment period until May 2, 2011.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding the meeting. 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.

Dated: March 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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