4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0206]

Center for Drug Evaluation and Research Medical Policy Council; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to receive suggestions, recommendations, and comments for topics from interested parties, including academic institutions, regulated industry, patient representatives, and other interested organizations, on medical policy issues that may be considered by the CDER Medical Policy Council (Council) in FDA's Center for Drug Evaluation and Research (CDER). These comments will help the Agency identify and address medical policy issues that need clarification through guidance, notice and comment procedures, or other means.

DATES: Submit either electronic or written comments by July 16, 2013.

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-301), 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:

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SUPPLEMENTARY INFORMATION:

I. Background

In January 2012, CDER established the Council to ensure better coordination of medical policy development and implementation within CDER and consistent, predictable communication of medical policy decisions to the public through guidance, notice and comment procedures, or other means.

Chaired by CDER's Associate Director for Medical Policy, the Council provides a senior-level forum through which medical policy issues can be raised, considered, developed, and implemented. Council members include the following senior clinical leaders: The Center Director, the Deputy Center Director for Clinical Science, the Director of the Office of New Drugs, and the Director of the Office of Surveillance and Epidemiology. Experts from within CDER and other FDA offices provide expertise as needed for specific policy topics under consideration. By establishing this docket, FDA encourages the public to recommend specific topics for consideration by the Council. The Agency believes that this process will also ensure additional transparency in CDER's approach to medical policy development and implementation.

II. Range of Medical Policy Issues to Be Considered

FDA envisions a variety of topics that may be relevant for consideration by the Council. Specific topics could address issues related to the following: (1) Clinical evidence of effectiveness or safety, (2) clinical study/trial design, (3) professional and patient labeling, (4) prescription drug promotion, (5) human subjects protection, (6) bioresearch monitoring, (7) good clinical practice, (8) counter-terrorism drug development (such as in the application of the Animal Rule, 21 CFR 314.600), and (9) postmarketing surveillance. To be considered by the Council, a medical policy issue typically would meet one or more of the following criteria:

- A novel medical policy issue requiring senior management input;
- an issue on which CDER seems to have taken inconsistent positions;
- an existing medical policy position that should be reconsidered in light of scientific or regulatory advances;
- a complex safety management issue requiring senior management input;
- a medical policy that may be triggered by a specific product, but that will be applicable to other products; or
- strategies for implementation of a new policy.

III. Establishment of a Docket and Request for Comments

FDA is requesting public suggestions, recommendations, and comments for topics (including scientific, clinical, regulatory, or other topics) on existing or novel medical policy issues that may warrant consideration by the Council. Comments should describe the following: (1) The medical policy issue recommended for discussion, (2) the rationale for doing so (e.g., clarifying previous advice or precedents, reconciling apparently differing perspectives within CDER or between CDER and regulated industry), (3) recommendations on how the medical policy issue could be addressed or implemented; and (4) existing policy documents (e.g., final

guidance) relevant to the medical policy issue. Note that policy issues concerning any draft guidance should be submitted to the docket for that draft guidance.

The Agency will carefully consider all comments submitted. FDA generally will not respond directly to the person or organization submitting the comment. In general, medical policy decisions reached by the Council are communicated and implemented in accordance with FDA's good guidance practices regulation (21 CFR 10.115) or notice and comment procedures.

IV. Request for Comments

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

Dated: March 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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