4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0813]

Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled "Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review" (literature review report). A literature review was conducted to address a requirement of the Patient Protection and Affordable Care Act (Affordable Care Act). FDA is publishing the literature review report to allow the public to provide comment on the report as it relates to the Affordable Care Act.

DATES: Submit either electronic or written comments on the literature review report by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. 2011-N-0813, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug 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 report entitled "Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review." A literature review was conducted to address section 3507 [1] of the Affordable Care Act (see http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf). Section 3507(a) requires the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (e.g., similar to "Drug

[1] Public Law, 111-148, 124 Stat. 119, 530 (codified at note following 21 U.S.C. 352).

Facts" on over-the-counter products) to the promotional labeling or print advertising of such drugs would "improve health care decisionmaking by clinicians and patients and consumers" (section 3507(a), Public Law 111-148, 124 Stat. 530). In making this determination, the law directs FDA to "review all available scientific evidence and research on decisionmaking and social and cognitive psychology" (section 3507(b), Public Law 111-148, 124 Stat. 530), and to consult manufacturers and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.

To fulfill this requirement, FDA has commissioned an objective review of science-based studies related to the communication of quantitative benefit and risk information. FDA is making available the literature review report and is providing a comment period for interested parties to comment on the literature review report as it relates to section 3507 of the Affordable Care Act.

II. Electronic Access

Persons with access to the Internet may obtain the literature review report at http://www.regulations.gov.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the literature review report. 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 and labeled "ATTN: Literature Review." Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

All submissions received must include the agency name and docket number. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

Dated: December 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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