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 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  

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

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.

[FR Doc. 2011-31931 Filed 12/12/2011 at 8:45 am; Publication Date: 12/13/2011]