DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.'' The draft guidance provides drug, biologics, and device manufacturers with the agency's views on the distribution of medical journal articles and scientific or medical reference publications that discuss unapproved new uses for FDA approved drugs or biologics or FDA approved or cleared medical devices to health care professionals and health care entities.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of Commissioner, Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic requests for copies of the draft guidance to *http://www.fda.gov/oc/op/goodreprint.html*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Office of Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices.'' The draft guidance provides drug, biologics, and device manufacturers with the agency's views on the distribution of medical journal articles and scientific or medical reference publications that discuss unapproved new uses for FDA approved drugs (including biologics) or FDA approved or cleared medical devices to health care professionals and health care entities.

On September 30, 2006, section 401 of the Food and Drug Administration Modernization Act (FDAMA) (section 551 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aaa)) ceased to be in effect. The provision described certain conditions under which a drug or medical device

manufacturer could disseminate medical and scientific information discussing unapproved uses of approved drugs and cleared or approved medical devices to health care professionals and certain entities (including pharmacy benefits managers, health insurance issuers, group health plans, and Federal or State governmental agencies). Section 401 of FDAMA provided that, if the described conditions were met, dissemination of such journal articles or reference publications would not be considered as evidence of the manufacturer's intent that the product be used for an unapproved new use. FDA implementing regulations were codified at 21 CFR part 99.

In light of the sunset of section 401 of FDAMA and in recognition of the public health value to health care professionals of receiving scientific and medical information, FDA is providing its current views and recommendations concerning ''Good Reprint Practices'' for the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of drugs and medical devices. FDA's legal authority to determine whether distribution of medical or scientific information constitutes promotion of an unapproved ''new use,'' or whether such activities cause a product to be misbranded or adulterated has not changed.

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 the dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to health care professionals and health care entities. 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**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that as of January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA only through FDMS.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 13, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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