DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0053]

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 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 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 healthcare professionals and healthcare entities.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD, 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Jarilyn Dupont, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4305, Silver Spring, MD, 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION:

I. Background

The 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 healthcare professionals and healthcare entities. In the **Federal Register** of February 20, 2008 (73 FR 9342), FDA announced the availability of a draft guidance for industry entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved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.'' FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized.

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 healthcare 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 healthcare professionals of receiving scientific and medical information, FDA determined that 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 were important. The sunset of the statutory provision eliminated the authority of FDA to require submission of articles for the agency's review before dissemination by the manufacturers in instances where the manufacturer chose to disseminate information under these provisions. In the absence of that ability to require such submissions and the fact that the implementing regulations are no longer applicable, the agency determined that guidance to manufacturers was appropriate because the agency no longer reviews individual articles.

With this guidance, FDA is providing its current views 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 healthcare professionals and healthcare entities. FDA's legal authority to determine whether certain distributions 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.

Some of the changes made to the guidance based on comments received, and on FDA's own initiative, include a specific reference encouraging manufacturers to seek approvals and clearance for new indications and intended uses for medical products. FDA recognizes the value of new indications and uses for approved products and wants these to be studied so that patients and healthcare professionals receive safe and effective treatments. Many comments suggested that FDA continue to require pre-submission of the articles and suggested other mandatory review practices. However, given the sunset of section 401 of FDAMA these were not within FDA's authority and thus outside the scope of this guidance. Section IV of the guidance clarifies a number of bullet points to address comments expressing confusion as to some of the terms and practices expressed. Additional information was provided to distinguish the dissemination of these types of articles from other industry practices.

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 dissemination of medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs and approved or cleared medical devices to healthcare professionals and healthcare 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 applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/op/goodreprint.html* or *http://www.regulations.gov.*

Dated: January 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0674]

Participation of Certain Population Subsets in Clinical Drug Trials; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and comments on issues related to the enrollment of certain populations in clinical drug trials. Particularly, we are requesting information and comments from medical product manufacturers, institutional review boards (IRBs), patient groups, universities, researchers, community groups, and other interested parties. This request is related to FDA's implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA) section 901, which requires recommendations be included in a report to Congress addressing best practice approaches on increasing the participation of elderly populations, children, racially and ethnically diverse communities, and medically underserved populations in clinical drug trials. FDA requests that those with information on possible approaches to increase participation of these groups in clinical drug trials submit comments.

DATES: Submit written or electronic comments by February 27, 2009.

ADDRESSES: Submit electronic comments 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.

FOR FURTHER INFORMATION CONTACT: Brenda Evelyn, Office of Special Health Issues, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4460.

SUPPLEMENTARY INFORMATION:

I. Background

Section 901 of FDAAA requires that FDA submit a report to Congress that includes ''recommendations regarding impediments to the participation of elderly populations, children, racially and ethnically diverse communities and medically underserved populations in clinical drug trials'' and recommendations that address ''best practice approaches for increasing the inclusion of such subsets of the general population'' in clinical drug trials (FDAAA, section 901(d)(5)). In developing this report, FDA seeks comments that may help to develop these recommendations.

Participation of all segments of the population in medical research is critical to public health. The ability to develop drugs that are safe and effective for diverse groups hinges on the availability of clinical drug trial participants from these same groups. Some researchers and public health experts argue that inconsistent representation of certain communities can potentially lead to health disparities and insufficient data for risk assessment. FDA has previously identified the need for inclusion of children, both sexes, the elderly, racially and ethnically diverse communities, and other populations in clinical trials so that data are available to evaluate the potential differences among these subgroups (63 FR 6854, February 11, 1998). According to the Department of Health and Human Services (HHS) Office of Minority Health, in a recent prostate cancer study, only 8 percent of the 18,000 participants were minorities (*www.omhrc.gov/templates/content.aspx?ID=5147*). Increased participation from all of these subgroups may help assure that data relevant to the entire treatment population are obtained.

In addition, statutory mandates and incentives such as the Pediatric Research Equity Act (PREA) (Public Law No. 108–155 as amended by FDAAA) and the Best Pharmaceuticals for Children Act (BPCA) (Public Law No. 107–109 as amended by FDAAA) require and encourage medical research to consider implications for pediatric populations.

For over 20 years, FDA has worked to encourage broad participation of all groups in clinical drug trials. Under FDA regulations (21 CFR 312.33), all investigational new drug (IND) applications must include in annual reports the number of patients tabulated by age, gender, and race, and under 21 CFR 314.50(d)(5)(v) and (d)(5)(vi), new drug applications (NDA) are required to include analyses of efficacy and safety by demographic subgroups. Biologics license applications typically include analyses of efficacy and safety by demographic subgroups. The International Conference on Harmonization (ICH) guidance on the common technical document also calls for such analyses (see M4E: The CTD—Efficacy (August 2001) available at *http://www.fda.gov/cber/gdlns/m4ectd.pdf*.).

FDA has issued labeling recommendations for specific subpopulations (Guidance for Industry: Content and Format of the Adverse Reactions Section of Labeling for Human Prescription Drugs and Biological Products, January 2006, available at *http://www.fda.gov/cber/gdlns/cfadvers.htm*) and guidelines for studying gender differences in clinical drug studies (Guideline for the Study and Evaluation of Gender, July 1993, available at *http://www.fda.gov/cder/Guidance/old036fn.pdf*). FDA has made recommendations for minimum standards for the collection and use of race and ethnicity information to assist in the reporting of the summary of safety and effectiveness data by demographic subgroups (age, gender, race), as well as an analysis of whether modifications of dose or dosage intervals are needed for specific subgroups. (Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials, September 2005, available at *http://www.fda.gov/CBER/gdlns/racethclin.htm*; see, also ICH E–7 Guideline for Industry, Studies in Support of Special Populations: Geriatrics (August 1994) available at