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Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved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 The draft guidance provides drug, biologics, and device manufacturers with the agency's views on the distribution of medical journal articles and scientific or medical reference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DATES: Submit written or electronic comments on the draft guidance by April 21, 2008. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit electronic requests for copies of the draft guidance to *http://www.fda.gov/oc/op/goodreprint.html*. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved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 The draft guidance provides drug, biologics, and device manufacturers with the agency's views on the distribution of medical journal articles and scientific or medical reference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.

[FR Doc. 08–746 Filed 2–15–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). To request a copy

of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Data Collection Tool for Rural Health Community-Based Grant Programs: (New)

The mission of the Office of Rural Health Policy (ORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (SEC. 711 of the Social Security Act. *[42 U.S.C. 912]*), Congress charged ORHP to ''administer grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.''

In 1991, the Health Service Outreach Grants were first appropriated, under the authority of Section 301 of the Public Health Service (PHS) Act. In 1996, the Health Centers Consolidation Act of 1996 added the Section 330A Rural Health Outreach Grant Program to the PHS Act. In 2002, this was amended and authorized again in the PHS Act, Section 330A, as the Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs. Five rural health grant programs are currently operating under this authority: (1) The Rural Health Care Services Outreach Grant Program (Outreach), (2) the Rural Health Network Development Program (Network Development), (3) the Small Health Care Provider Quality Improvement Grant Program (Quality), (4) the Delta States Rural Development Network Grant Program (Delta), and (5) the Network Development Planning Grant Program (Network Planning). These grants are to provide expanded delivery of health care services in rural areas, for the planning and implementation of integrated health care networks in rural areas, and for the planning and implementation of small health care provider quality improvement activities.

In general, the grants may be used to expand access to, coordinate, and improve the quality of essential health care services, and enhance the delivery of health care, in rural areas.

For these programs, program performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principle topic areas of interest to ORHP, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health-related clinical measures. Several measures will be used for all five programs. All measures will speak to the Office's progress toward meeting the goals set forth in its strategic plan.

The annual burden estimate for this proposed collection is as follows:

Grant program	Number of respondents	Frequency of responses	Total responses	Hours per response	Total hour burden
Rural Health Outreach Grant Program	121	1	121	1.25	151.25
Rural Health Network Development	33	2	66	4	264
Delta States Rural Development Network Grant Program	12	1	12	1.25	15
Small Health Care Provider Quality Improvement Grant Program	15	1	15	1	15
Network Development Planning Grant Program	10	1	10	4	40
Total	191		234		525.25

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: February 12, 2008.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E8–3064 Filed 2–19–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Date: March 14, 2008.

Time: 9 a.m. to 4 p.m.

Agenda: Discussion of IACC Strategic Plan for Autism Spectrum Disorder Research and responsibilities of the IACC under the Combating Autism Act.

Place: Ronald Reagan Building and International Trade Center, Rotunda, North Tower, 8th Floor, 1300 Pennsylvania Avenue, NW., Washington, DC 20004, Phone: 202–312–1300.

Contact Person: Tanya Pryor, Interagency Autism Coordinating Committee, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6187, MSC 9669, Bethesda, MD 20892–9669, (301) 443–7153, *pryort@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, all guests and vehicles are screened upon entry into the underground parking garage at the Ronald Reagan Building. Please allow extra time for this process.