they file their new entrant reports prior to assuming Government responsibilities.

Each filing is estimated to take an average of one and one-half hours. The number of private citizens whose reports are filed each year with OGE is less than 10, but pursuant to 5 CFR 1320.3(c)(4)(i), the lower limit for this general regulatory-based requirement is set at 10 private persons (OGEprocessed reports). This yields an annual reporting burden of 15 hours, the same as in the current OMB inventory for this information collection. The remainder of the private citizen reports are filed with other departments and agencies throughout the executive branch.

Public comment is again invited on each aspect of the proposed new OGE Form 450 as set forth in this second notice, including specifically views on the need for and practical utility of this proposed modified collection of information, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The Office of Government Ethics, in consultation with OMB. will consider all comments received, which will become a matter of public record.

Approved: November 30, 1995. Donald E. Campbell,

Deputy Director, Office of Government Ethics. [FR Doc. 95–29723 Filed 12–5–95; 8:45 am] BILLING CODE 6345–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D-0377]

Advertising and Promotion; Draft Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing two draft guidance documents entitled "Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data" and "Guidance for Industry Funded Dissemination of Reference Texts." These draft guidances are related to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products, of certain reprints of journal articles discussing FDA-approved products, and reference texts (medical textbooks and compendia). The draft guidances describe circumstances under which the agency would exercise its discretion to allow the dissemination of these reprints and reference texts to health care professionals.

DATES: Written comments by January 5, 1996.

ADDRESSES: Submit written comments on the draft guidance documents to the Dockets Management Branch (HFA– 305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, or FAX at 301– 594–3215.

FOR FURTHER INFORMATION CONTACT: Ilisa B. G. Bernstein, Office of Policy (HF– 23), Food and Drug Administration, 5600 Fishers Lane, rm. 15–74, Rockville, MD 20857, 301–827–3380, or via internet at IBernste@bangate.fda.gov.

SUPPLEMENTARY INFORMATION: Health care professionals have always been able to obtain, from a number of different sources, journal articles and reference texts (i.e., medical textbooks and compendia), that discuss human and animal drugs, medical devices, and biological products. These journal articles and reference texts are commercially available and may be obtained from publishers, libraries, online data bases, colleagues, bookstores, companies upon request, or other sources. Sponsors of human and animal drugs, medical devices, and biological products frequently have expressed a desire to disseminate reprints of journal articles and reference texts to health care professionals.

FDA traditionally has taken the position that sponsors who wish to distribute articles and reference texts containing information that is inconsistent with the FDA-approved labeling for a product may be in conflict with the Federal Food, Drug, and Cosmetic Act and implementing regulations. The agency's position is based on its mission to help ensure the safety and efficacy of human and animal drugs, medical devices, and biological products. Sponsors seeking approval or clearance to market these products must demonstrate to FDA that the products are safe and effective for their intended use(s). Permitting sponsors to freely disseminate information that is inconsistent with the FDA-approved or cleared use(s) would diminish the incentive for sponsors to perform the clinical studies which are necessary to verify that the product is safe and effective for the unapproved use. Furthermore, information disseminated by a biased source may have a greater

potential to mislead the health care professional.

FDA believes that journal articles and reference texts are often useful to health care professionals. Accordingly, the agency has reviewed its policies to determine if modifications can be made without jeopardizing the integrity of the statutorily mandated standard that marketed drugs be safe and effective and have adequate directions for their intended use(s). After careful review, the agency is proposing to modify two of its policies at this time.

First, under one proposed draft guidance, the agency would allow sponsors to disseminate, under certain circumstances, journal articles that report the results of well-controlled studies, provided they represent the peer-reviewed, published version of original efficacy trials used to support approval, licensure, or clearance. Second, under the other proposed draft guidance, the agency would allow sponsors to disseminate, under certain circumstances, reference texts that discuss human or animal drugs, medical devices, or biological products. FDA has prepared two draft guidance documents describing the proposed circumstances under which the agency would exercise its discretion regarding the dissemination of these materials by sponsors.

FDA is particularly interested in receiving comments on whether the reprints discussed in the "Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data" should be from "peer-reviewed" journals. If so, please comment on what constitutes a "peer-reviewed" journal and what benefits would be afforded if these reprints are from "peer-reviewed" journals.

Interested persons may, on or before January 5, 1996, submit to the Dockets Management Branch (address and FAX number above) written comments on the draft guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance documents and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The texts of the draft guidance documents follow: