Federal Reserve Bank of New York as follows:

The information reviewed at this meeting suggests that economic activity is expanding at a moderate rate in the current quarter. Nonfarm payroll employment increased considerably in August after essentially no growth in July; the civilian unemployment rate edged down to 5.6 percent in August. Industrial production posted a large increase in August to a level moderately above the average of the second quarter. Total nominal retail sales rose slightly on balance over July and August after registering appreciable gains in the prior two months. Housing starts were up a little in August after increasing sharply in July. Orders for nondefense capital goods have softened but still point to substantial expansion of spending on business equipment over coming months; nonresidential construction has been strong of late The nominal deficit on U.S. trade in goods and services widened slightly in July from its average rate in the second quarter. After increasing at elevated rates in the early part of the year, consumer and producer prices have risen more slowly in recent months.

Market interest rates have fallen somewhat since the Committee meeting on August 22. In foreign exchange markets, the trade-weighted value of the dollar in terms of the other G–10 currencies has declined over the intermeeting period, with most of the decline occurring over the past several days.

M2 and M3 continued to register sizable increases in August but growth of those aggregates appears to have moderated somewhat in September. For the year through August, M2 expanded at a rate somewhat below the upper end of its range for 1995 and M3 grew at a rate appreciably above its range. Total domestic nonfinancial debt has grown at a rate around the midpoint of its monitoring range in recent months.

The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. In furtherance of these objectives, the Committee at its meeting in July reaffirmed the range it had established on January 31-February 1 for growth of M2 of 1 to 5 percent, measured from the fourth quarter of 1994 to the fourth quarter of 1995. The Committee also retained the monitoring range of 3 to 7 percent for the year that it had set for growth of total domestic nonfinancial debt. The Committee raised the 1995 range for M3 to 2 to 6 percent as a technical adjustment to take account of changing intermediation patterns. For 1996, the Committee established on a tentative basis the same ranges as in 1995 for growth of the monetary aggregates and debt, measured from the fourth quarter of 1995 to the fourth quarter of 1996. The behavior of the monetary aggregates will continue to be evaluated in the light of progress toward price level stability, movements in their velocities, and developments in the economy and financial markets.

In the implementation of policy for the immediate future, the Committee seeks to maintain the existing degree of pressure on reserve positions. In the context of the Committee's long-run objectives for price stability and sustainable economic growth, and giving careful consideration to economic, financial, and monetary developments, slightly greater reserve restraint or slightly lesser reserve restraint would be acceptable in the intermeeting period. The contemplated reserve conditions are expected to be consistent with growth in M2 and M3 over the balance of the year near the pace of recent months.

By order of the Federal Open Market Committee, November 27, 1995.

Donald L. Kohn,

Secretary, Federal Open Market Committee.

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which include the domestic policy directive issued at that meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's annual report.

OFFICE OF GOVERNMENT ETHICS

Submission of Proposed Modified Form for Executive Branch Confidential Financial Disclosure Reporting to OMB for Approval Under the Paperwork Reduction Act

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice.

SUMMARY: The Office of Government Ethics has submitted a proposed new OGE Form 450 for confidential financial disclosure reporting under its executive branch regulations for approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. This new form will replace the existing Standard Form (SF) 450.

DATES: Comments on this proposal should be received by January 5, 1996.

ADDRESSES: Comments should be sent to Joseph F. Lackey, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; telephone: 202–395–7316.

FOR FURTHER INFORMATION CONTACT: William E. Gressman, Office of the General Counsel and Legal Policy, Office of Government Ethics, 1201 New York Avenue, NW., Washington, DC 20005–3917; telephone: 202–523–5757 (ext. 1110), FAX: 202–523–6325. A copy of OGE's draft form, as well as the rest of OGE's paperwork submission package to OMB, may be obtained, without charge, by contacting Mr. Gressman.

SUPPLEMENTARY INFORMATION: The Office of Government Ethics is submitting a proposed new OGE Form 450 Executive Branch Confidential Financial Disclosure Report for three-year approval by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). On September 1, 1995, OGE published an advance paperwork notice of the proposed new OGE Form 450 (see 60 FR 45722–45723). During the public comment period on that advance notice, OGE received seven requests by persons outside OGE for copies of the proposed new form and two comment letters, both of which were from Federal agencies (the Nuclear Regulatory Commission and the Defense Logistics Agency (DLA)). The two comment letters generally questioned certain aspects of the confidential financial disclosure system, including the underlying OGE regulation codified at 5 CFR part 2634. The comment letters also urged a few specific changes to the wording or concepts of the proposed form. Upon review, OGE has determined not to modify the underlying reporting format nor the proposed form itself (except, as to the form, for a couple of clarifying revisions). In part in response to certain DLA suggestions, the revisions to the proposed form add references in the instructions (on page 2) to the reporting of ''401k'' plans and clarify that the individual holdings of such plans as well as Individual Retirement Accounts and trusts must generally be reported. The Office of Government Ethics' reasons for not otherwise modifying either the proposed form or the underlying regulation follow.

The Office of Government Ethics has already removed, by FR issuance, the requirement for reporting of Government securities, bank accounts and certain similar items which do not normally present much potential for a conflict of interest. See below for a discussion of this 1993 change, which is not reflected in the existing SF 450, but will be in the proposed OGE Form 450. In addition, in the three years since the

new executive branchwide confidential disclosure system took effect in the fall of 1992, the overall system has worked well according to the agency feedback that OGE has received. This is particularly so since OGE and the agencies have been flexible within the regulatory framework, allowing for appropriate limitations on coverage, exceptions and alternative forms where justified. Further, OGE is committed to a future fundamental reassessment of the basic structure of the confidential disclosure system. For now, though, the redesigned proposed OGE Form 450 represents urgently needed improvements and updates to the existing Standard Form 450 which it will replace.

As noted, once finally approved by OMB and adopted by OGE, the new OGE form will replace the existing SF 450 Executive Branch Personnel Confidential Financial Disclosure Report. The SF 450 collects, as will the future OGE Form 450, information required under OGE's executive branchwide regulatory provisions. See subpart I of 5 CFR part 2634. The new OGE Form 450 will serve, as does the current SF 450, as the uniform report form for collection, on a confidential basis, of financial information required by the OGE regulation from certain new entrant and incumbent employees of the executive branch departments and agencies in order to allow ethics officials to conduct conflict of interest reviews and to resolve any actual or potential conflicts found.

The basis for the OGE regulation and the report form is two-fold. First, section 201(d) of Executive Order 12674 of April 12, 1989 (as modified by Executive Order 12731 of October 17, 1990) makes OGE responsible for the establishment of a system of nonpublic (confidential) financial disclosure by executive branch employees to complement the system of public disclosure under the Ethics in Government Act of 1978 (the ''Ethics Act''), as amended, 5 U.S.C. appendix. Second, section 107(a) of the Ethics Act further provides authority for OGE as the supervising ethics office for the executive branch of the Federal Government to require that appropriate executive agency employees file confidential financial disclosure reports, ''in such form as the supervising ethics office may prescribe.'' The current SF 450, together with the underlying OGE confidential disclosure regulation, both initially adopted in 1992 after appropriate clearances from OMB as well as the General Services Administration (GSA) for the standard form, constitute the form OGE has prescribed for such confidential financial disclosure in the executive branch. The Office of Government Ethics recently sought and subsequently obtained a limited paperwork renewal from OMB as to the existing SF 450 in order to allow sufficient time for OGE to develop and clear the new OGE Form 450 which is the subject of this notice. See 60 FR 34258–34259 (June 30, 1995). The new OGE form will not require GSA clearance, since it is not a standard (or optional) form under the GSA program. The Office of Government Ethics will provide further information in the future to the agencies and the public about the details of phasing in the new form, once it is finally cleared and adopted, and phasing out the existing standard form.

Since the OGE's financial disclosure regulation at 5 CFR part 2634 and the reporting format were adopted in 1992, there have been certain revisions to each. The most significant of these is the determination of OGE to exclude from general executive branch confidential financial disclosure the reporting of cash accounts in depository institutions (including banks), money market mutual funds and accounts and U.S. Government obligations and securities. See 58 FR 63023–63024 (November 30, 1993). The Office of Government Ethics has directed executive departments and agencies to notify all filers of this change, which is not reflected on the SF 450 itself. The new OGE replacement form will reflect that change, as well as various other changes and improvements in the reporting format, to make it clearer and more user-friendly. A more complete set of instructions for filling out the form is included in the draft OGE Form 450 and helpful examples are set forth on the reporting parts.

The Office of Government Ethics expects that the new form should be ready, after OMB clearance, for dissemination to executive branch departments and agencies early next year. As noted above, the Office of Government Ethics will provide appropriate guidance and phase-in time to departments and agencies once the new form is available. The new form will be made available in paper, on electronic disk and on OGE's electronic bulletin board entitled ''The Ethics Bulletin Board System'' (TEBBS). In addition, OGE will work on making available a future electronic version of the form, to allow employees the option of preparing it on a computer. The Office of Government Ethics also intends to permit departments and agencies to develop or utilize electronic versions of the form on their own, provided that they precisely duplicate the paper original to the extent possible.

Since 1992, various agencies have developed, with OGE review/approval, alternative reporting formats, such as certificates of no conflict, for certain classes of employees. Other agencies provide for additional disclosures pursuant to independent organic statutes and in certain other circumstances when authorized by OGE. However, the future OGE Form 450, as successor to the current SF 450, will remain the uniform executive branch report form for most of those executive branch employees who are required by their agencies to report confidentially on their financial interests. The confidential report form is to be filed by each reporting individual with the designated agency ethics official at the executive department or agency where he or she is or will be employed.

Reporting individuals are regular employees whose positions have been designated by their agency as requiring confidential financial disclosure in order to help avoid conflicts with their assigned responsibilities; additionally, all special Government employees (SGEs) are generally required to file. Agencies may, if appropriate under the OGE regulation, exclude certain regular employees or SGEs as provided in 5 CFR 2634.905. Reports are normally required to be filed within 30 days of entering a covered position (or earlier if required by the agency concerned), and again annually if the employee serves for more than 60 days in the position. As indicated in § 2634.907 of the OGE regulation, the information required to be collected includes assets and sources of income, gifts and travel reimbursements, liabilities, employment agreements and arrangements, and outside positions, subject to certain thresholds and exclusions.

Most of the persons who file this report form are current executive branch Government employees at the time they complete the forms. However, some filers are private citizens who are asked by their prospective agency to file a new entrant report prior to entering Government service in order to permit advance checking for any potential conflicts of interest and resolution thereof by agreement to recuse, divest, obtain a waiver, or take other remedial steps. Based on OGE's annual agency ethics questionnaire responses, approximately 285,000 SF 450 report forms were filed during 1994 throughout the executive branch. Of these, OGE estimates that no more than between 5% and 10%, or some 14,250 to 28,500 per year, are filed by private citizens whose agencies require that

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 (OGE-processed 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, on-line 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: