by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 26, 1997 (62 FR 50497), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0352. The approval expires on November 30, 2000.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–075 Filed 1-2-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0506]

Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only.'' The purpose of the CPG is to provide guidance on FDA's enforcement priorities concerning investigational or research IVD's that are being commercialized for diagnostic or prognostic purposes.

DATES: Written comments on the draft CPG may be submitted by April 6, 1998.

ADDRESSES: Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft CPG to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 (301–443–6597 or outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Facsimiles of the draft CPG are available from the Division of Small Manufacturers Assistance, CDRH. To receive the draft CPG on your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press ''1'' to access DSMA Facts, at the second voice prompt press ''2,'' and then enter the document number, ''671,'' followed by the pound sign, ''#''. Follow the remaining voice prompts to complete the request. Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CDRH Home Pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'' respectively. The draft CPG will be available on the Compliance References or Compliance Information pages for ORA and CDRH respectively.

FOR FURTHER INFORMATION CONTACT: Betty W. Collins, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4588, ext. 165.

SUPPLEMENTARY INFORMATION: FDA has developed a draft CPG to provide guidance on FDA's enforcement priorities concerning investigational or research IVD's that are being commercialized for diagnostic or prognostic purposes. This draft CPG applies to IVD's sold or distributed as test kits. Many manufacturers of IVD's have not followed the requirements set forth in parts 809 and 812 (21 CFR parts 809 and 812). As a result, numerous IVD's labeled for research or investigational purposes are being promoted, distributed, and used for commercial purposes. This has resulted in the widespread use of laboratory tests with unproven performance characteristics. Unless exempted from the requirement to submit premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(k)), IVD's that are commercially distributed for diagnostic use prior to FDA approval or clearance are adulterated and misbranded under sections 501(f)(1)(B) and 502(o) of the act (21 U.S.C. 351(f)(1)(B) and 352(o)). Such distribution subjects the devices and responsible firms to regulatory action.

However, FDA recognizes that certain improperly commercialized IVD's have been in extensive clinical use for a significant period of time. FDA further recognizes that immediate regulatory action against certain IVD's might result in adverse consequences to individual patients and the public health. Therefore, FDA has prepared a draft CPG in order to describe its enforcement policy. Except in specified instances, FDA does not intend to initiate enforcement action, for 18 to 30 months from the **Federal Register** publication date of the notice of availability (NOA) for the final CPG on commercialization of IVD's labeled for research use only or investigational use only, against IVD's that have not been approved or cleared, provided the IVD manufacturers, importers, and distributors take steps and obtain FDA approval of a premarket approval application, product license application, or clearance of a premarket notification submission under section (510(k)) of the act during that time period. Those steps include undertaking, by 6 months from the **Federal Register** publication date of the NOA for the final CPG, any necessary clinical investigations or other studies under a protocol sufficient to allow determination of the IVD's safety and effectiveness. FDA believes that the 18- to 30-month time period is a reasonable period for gathering safety and effectiveness data and obtaining FDA approval or clearance. This draft CPG applies to IVD's that are regulated by FDA's CDRH and Center for Biologics Evaluation and Research, and supersedes FDA's earlier draft made public in June 1996.

This draft CPG does not cover analyte specific reagents (ASR's) that, as specified under §§ 809.10(e), 809.30, and 864.4020 (21 CFR 864.4020), are not labeled or promoted with performance claims, and are sold to: (1) In vitro diagnostic manufacturers; (2) clinical laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 as qualified to perform high complexity testing under 42 CFR part 493 or clinical laboratories regulated under the Veterans Health Administration Directive 1106; and (3) organizations that use the ASR to make tests for purposes other than providing diagnostic information to patients and practitioners. ASR's are defined as

antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. FDA's final rule on ASR's was published in the **Federal Register** of November 21, 1997 (62 FR 62243).

Additionally, this draft CPG does not pertain to in vitro products whose use is limited to laboratory research that is entirely unrelated to the development of IVD's.

This draft guidance document represents the agency's current thinking on commercialization of in vitro diagnostic devices labeled for research use only or investigational use only. 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 statute, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft CPG entitled ''Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only.'' 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 agency will review all comments, but in issuing a final CPG, need not specifically address every comment. The agency will make changes to the CPG in response to comments, as appropriate. A copy of the draft CPG and received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 1997.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 98–011 Filed 1-2-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0525]

Draft Guidance for Industry: ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)''

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 ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs).'' This document provides guidance to sponsors of regulated medical products (human drugs, biologics, and medical devices) by describing circumstances in which sponsors may be held responsible for promotional activities performed by healthcare organizations or PBM's that violate the Federal Food, Drug, and Cosmetic Act (the act) and regulations issued thereunder. The intent of this draft guidance is to provide clarification and consistency in the agency's regulation of medical product promotion in light of changes in the healthcare environment.

DATES: Written comments may be submitted on the draft guidance document by April 6, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: An electronic version of this draft guidance is available on the Internet using the World Wide Web (WWW) at http://www.fda.gov/cder/guidance.htm. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft guidance for industry entitled ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription drugs: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, or via Internet at burkel@cder.fda.gov;

Regarding prescription biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at stifano@cber.fda.gov;

Regarding restricted medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639, or via Internet at bxt@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA's Guidance Document Development Process

On March 28, 1997, as part of the agency's ongoing efforts to ensure meaningful public participation in the guidance document development process, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) requested public comment on guidance documents relating to prescription drug advertising and labeling (Ref. 1). Included in the list of currently proposed guidance documents was ''Promotion to Managed Care Organizations.'' The draft guidance document now being made available is the first draft document to be issued on this topic and addresses only one aspect of promotion to managed care, i.e., promotion by healthcare organizations or PBM's. Other related draft guidance documents will be issued separately under the general heading ''Promoting Medical Products in a Changing Healthcare Environment.''

B. Statutory and Regulatory Requirements

Under the act, FDA has responsibility for regulating the labeling and, in many cases, the advertising of medical