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This draft guidance document represents the agency's current thinking on commercialization of in vitro diagnostic devices labeled for research use only or investigational use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

BILLING CODE 4160–01–F

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Draft Guidance for Industry: ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy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

products (human drugs, biologics, and medical devices). Section 301 of the act (21 U.S.C. 331) prohibits the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug or device and of an unapproved new drug; the adulteration or misbranding of a drug or device in interstate commerce; and the doing of any act that results in the adulteration or misbranding of a drug or device while such article is held for sale after shipment in interstate commerce. The introductory phrase of section 301 provides that the ''causing'' of any prohibited act, as well as the act itself, is prohibited.

A drug or device is misbranded if its labeling is false or misleading (section 502(a) of the act (21 U.S.C. 352(a)) or if its labeling fails to bear adequate directions for use (section 502(f) of the act). A change or modification in the intended use of a device may cause the device to be adulterated (section 501(f)(1)(B) of the act (21 U.S.C. 351(f)(1)(B)) and misbranded (section 502(o) of the act). Labeling and advertising include promotional information that is disseminated by a sponsor or by other persons on behalf of the sponsor (see 21 CFR 202.1(l)(1) and (l)(2)).

C. FDA's Information-Gathering Activities

In August 1994, FDA invited four product sponsors to meet with the agency individually to discuss regulatory issues in light of their newly established relationships with PBM's. Since that time, FDA has continued to gather information about changes in the process of healthcare delivery. In so doing, the agency has participated in programs, meetings, and workshops with managed care experts and other parties, including medical product sponsors, managed care organizations, academia, consumer advocacy groups, and health professional organizations. FDA has also participated in the design and review of studies and reports funded and/or performed by other Federal organizations to address various aspects of medical benefits management. These organizations included the Health Care Financing Administration (HCFA), the Office of the Inspector General of Health and Human Services (OIG–HHS), and the Federal Trade Commission (FTC) staff. FDA has also reviewed documents pertaining to the General Accounting Office (GAO) and the National Association of Attorneys General (NAAG) investigations, as well as court proceedings that examined contractual arrangements between medical product sponsors and other healthcare entities.

On October 19 and 20, 1995, FDA held a public hearing on ''Pharmaceutical Marketing and Information Exchange in Managed Care Environments'' (Ref. 2). The purpose of this hearing was to solicit information and views concerning the potential impact of changing organizational structures and information dissemination channels in the managed care setting on the agency's responsibilities to regulate drug marketing and promotion. FDA heard testimony from 26 individuals representing sponsors, PBM's, managed care organizations, national pharmacy organizations, advertising agencies, academia, law firms, State and Federal agencies, and consumer advocacy groups. The agency reviewed an additional 38 comments from similar organizations that were submitted to the hearing docket. Since the public hearing, the agency has held individual discussions about the changing healthcare environment with representatives from the pharmaceutical industry, a State attorney general's office, retail and institutional pharmacists, representatives from several professional organizations, representatives from several consumer advocacy organizations, and representatives from medical insurer organizations who provide pharmacy benefits. FDA continues to participate in several interagency work groups that address policy development issues relevant to the influence of managed care.

II. FDA's Findings Regarding Changes in the Healthcare Environment That Affect FDA's Regulation of Medical Product Promotion

As a result of the activities outlined in section I.C of this document, several important changes in the healthcare marketplace were identified that affect FDA's regulatory approach with respect to promotional labeling and advertising. One such change is the acquisition of healthcare provider organizations and PBMs by medical product sponsors. Because of public concern about the effects of the merger of pharmaceutical sponsors with PBM's, GAO investigated, among other things, the objectives of these mergers. GAO reported that ''drug manufacturers have merged or allied with PBMs because they believe that the PBMs' market power will help maintain the manufacturers' profits at a time when their drugs face increased competition.'' GAO also reported that, in order ''to bolster profits, manufacturers are relying on their PBM partners to help them increase market share for their drugs and develop new programs for treating specific diseases (Ref. 3).'' This type of environment fosters medical product promotion by sponsor-controlled PBM's on behalf of the sponsor.

In 1995, FTC issued a consent order to address the antitrust implications of Eli Lilly's (the Lilly Order) acquisition of the PCS Health System (PCS), a large PBM. The FTC's Order was intended to minimize anticompetitive foreclosure by ensuring that PCS customers have an alternative to sponsor-controlled formularies. The Lilly Order therefore requires, among other things, that PCS offer an ''open'' formulary that is compiled by an independent pharmacy and therapeutics (P&T) committee utilizing only objective criteria. However, the Order does not restrict or ensure independence in the promotional practices of sponsor-controlled PBM's. Furthermore, FTC's Order explicitly permits Lilly-PCS to offer other more restrictive formularies to its customers and places no restrictions on the selection of drug products for those formularies.

In addition to corporate ownership, many sponsors are pursuing marketing affiliations and pricing agreements with PBM's and other healthcare provider organizations. Some of these agreements provide product-specific incentives for the provider organizations to influence prescribing decisions. In some cases, patients on chronic drug therapy are switched from one product to another as a result of these incentives. Some agreements include variable pricing (via rebates) according to market share growth attained (Ref. 4). In an effort to affect the market share of specific products, a healthcare provider organization may enforce restrictions on prescribing decisions or disseminate promotional materials designed to influence prescribing decisions toward particular products and away from their competitors (Ref. 5).

Additionally, PBM's are expanding their role beyond claims processing and mail-order pharmacy to other activities, such as treatment intervention and disease management programs. These activities include compiling and furnishing a wide range of materials about medical products to their clients (healthcare plans and providers) with the intent of providing information and services that will influence clinical outcomes and control healthcare costs (Ref. 6).

As a result, promotional activities of medical product sponsors are often focused on managed care's demand for product-specific information.

Increasingly, promotional activities are being directed to, and channeled through, providers who make coverage policies and treatment recommendations for groups of insured individuals in managed healthcare organizations. Coverage policies may include the use of specified drug formularies [1] or preferred product lists. [2] Treatment recommendations or decisions may be enforced by a number of interventions, (Ref. 7) such as the dissemination of materials to healthcare providers and patients, implementation of disease management [3] programs, prior authorization requirements, [4] interchange programs, [5] and drug utilization reviews. [6] The incentive to promote medical products is extended by product sponsors to other persons in cases where contracts include sliding rebate scales based on the proportion of claims processed that conform to the formulary or declared product preferences (Ref. 8).

FDA was told at the October 1995 public hearing that promotional efforts are now being directed toward P&T committee members in hopes of influencing decisions about formulary inclusion of particular product(s) (Ref. 9). FDA is also aware that some benefits management companies who have business relationships with medical product sponsors are distributing product-specific information to P&T committees (as well as to managed care professionals and patients) that is false or misleading and would be considered violative if distributed directly by the product sponsor (Ref. 10).

[1] A formulary is a list of drug products. An open formulary includes all (or nearly all) available products yielding a minimal amount of formulary restrictiveness. A closed formulary is a limited list of drugs approved for use or covered under the drug plan.

[2] A preferred product list is sometimes called a ''managed'' formulary because, even though product use is unrestricted, incentives exist to increase utilization of the ''preferred'' products. Insurers and their clients often benefit financially from the use of preferred products through rebates from manufacturers and reduced drug costs.

[3] Disease management directs product use and patient behaviors to minimize the total cost of illness and improve medical and pharmaceutical care.

[4] Prior authorization is a mechanism to restrict the use of services by requiring advance approval before coverage is granted.

[5] Interchange programs direct treatment choices to preferred products at the point of dispensing or product use.

[6] Utilization review interventions change patterns of product use by contacting the clinician who ordered the product. Utilization review may be retrospective or prospective at the point of dispensing or product use. Educational tools may be included.

A survey of 368 health maintenance organization (HMO) decisionmakers [7] in the United States (Ref. 11) found that the biggest concern of HMO's about PBM's is the potential for bias resulting from alliances of the PBM's with drug manufacturers. Preferred or restricted product lists or formularies are sometimes established without objective criteria and without review by independent bodies who utilize deliberative scientific decisionmaking processes (Ref. 12). In some situations, formulary decisions are made to serve the economic needs of the healthcare organization or of the sponsors whose drugs are found on those formularies (Ref. 13). Despite the concerns of HMO's, however, HMO's rely primarily on PBM-supplied data and reports for overseeing performance of their PBM's. They rely less on independent assessments from their own clinicians and patients (Ref. 14).

III. Conclusions

During the past several years, there have been many changes in the way healthcare is delivered and in the role medical product sponsors play in that marketplace. For example, some product sponsors have acquired or entered into agreements with healthcare organizations or PBM's. Medical product sponsors often cause subsidiaries and other persons acting on their behalf to participate in promotional activities, including the dissemination of promotional labeling and advertising, and, in some instances, such arrangements are utilized as a means to avoid regulatory oversight of these activities.

FDA is particularly concerned about promotional activities that may create a public health risk. For example, promotional materials disseminated to healthcare providers and patients may result in inappropriate medical decisions if the information is false, misleading, or promotes an unapproved use. FDA is also concerned that sponsors are not submitting all such materials to the agency under the existing postmarketing reporting requirements. Furthermore, FDA seeks to maintain ''a level playing field'' for all medical product sponsors with respect to the regulation of their promotional activities. In public testimony, a pharmaceutical industry representative suggested to FDA that sponsors should be held accountable for promotional material related to their product(s) even when such material is prepared by or disseminated through a PBM or other healthcare provider (Ref. 15).

[7] An HMO decisionmaker represented either the chief executive or head pharmacy services.

Therefore, this draft guidance document clarifies circumstances in which FDA may hold a medical product sponsor responsible for promotional activities performed by a healthcare organization/PBM subsidiary of the sponsor, and by a nonsubsidiary healthcare organization/PBM on behalf of the sponsor that violate the act and regulations. The draft guidance lists several factors that the agency will use to determine sponsor responsibility for medical product promotion performed by a nonsubsidiary healthcare organization/PBM on behalf of the sponsor.

The draft guidance for industry also reminds medical product sponsors of their responsibility to submit or, in the case of some devices maintain historical files of, promotional labeling and advertising. This responsibility includes those activities performed by subsidiaries or, in certain cases, by healthcare organizations/PBM's.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Prescription Drug Advertising and Promotional Labeling, Development and Use of FDA Guidance Documents; Request for Comments,'' (62 FR 14912 to 14917, March 28, 1997).

2. ''Pharmaceutical Marketing and Information Exchange in Managed Care Environments, Public Hearing,'' (60 FR 41891 to 41893, August 14, 1995).

3. Pharmacy Benefit Managers, Early Results on Ventures with Drug Manufacturers, United States General Accounting Office, Washington, DC 20548, GAO/HEHS–96–45, November 195.

4. ''Assessment of the Impact of Pharmacy Benefit Managers,'' HCFA–95–023/PK, September 30, 1996.

5. Testimony by Stephen Stefano, Vice President and General Manager, Health Management Division, Glaxo Wellcome, at FDA public hearing, p.25, October 19, 1995.

6. Testimony by Per Lofberg, President, Medco Containment Services, at FDA public hearing,
p. 43, October 20, 1995.

7. ''Assesment of the Impact of Pharmacy Benefit Managers,'' HCFA–95–023/PK, September 30, 1996.

8. *See Pfizer, Inc.* v. *PCS Health Sys., Inc.*, No. 126154/95 (N.Y. Sup. Ct. October 27, 1995).

9. Testimony by Richard Jay, Vice President of Corporate Pharmacy Services, FHP, Inc., and representing the Group Health Association of America (GHAA), at FDA public hearing, p. 14, October 20, 1995. (This association is currently called the American Association of Health Plans (AAHP).)

10. Testimony by Stephen Stefano, Vice President and General Manager, Health Management Division, Glaxo Wellcome, at FDA public hearing, October 19, 1995, p. 22; and complaints directed to DDMAC by other drug sponsors.

11. Brown, J. G., ''Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies,'' Department of Health and Human Services Office of Inspector General, Office of Evaluation and Inspections, Boston Regional Office; OEI–01–95–00110; April 1997.

12. *See Pfizer, Inc.* v. *PCS Health Sys., Inc.*, No. 126154/95 (N.Y. Sup. Ct. October 27, 1995) (Pfizer Complaint).

13. *See Pfizer, Inc.* v. *PCS Health Sys., Inc.*, No 126154/95, at 5–11 (N.Y. Sup. Ct. November 21, 1995) (Pfizer's supplemental memorandum).

14. Brown, J. G., ''Experiences of Health Maintenance Organizations with Pharmacy Benefit Management Companies,'' Department of Health and Human Services Office of Inspector General, Office of Evaluation and Inspections, Boston Regional Office; OEI–01–95–00110; April 1997.

15. Testimony by Stephen Stefano, Vice President and General Manager, Health Management Division, Glaxo Wellcome, at FDA public hearing, October 19, 1995, p. 21–22; and a complaint directed to DDMAC by another pharmaceutical sponsor.

V. Comments

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–85 Filed 1–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–66]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: March 6, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, S.W., Room 4238, Washington, DC 20420–5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708–3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Demolition/Disposition Application.

OMB Control Number: 2577–0075.

Description of the need for the information and proposed use: Housing Agencies (HAs) are required to submit this information to HUD to request permission to demolish or sell all or a portion of a development (i.e., dwelling units, non-dwelling property or vacant land) owned and operated by a HA. The specific information requested in the application is based on requirements of the statute, Section 18 of the United States Housing Act of 1937, as amended, and specifically identified in 24 CFR Part 970 of the regulation. The Department uses the information submitted to determine whether, and under what circumstances, to permit a HA to demolish or sell all or a portion of a public housing development. Since there is no handbook on demolition/disposition of public housing, in the past, the only resource available to HAs for guidance on preparation of the application has been the regulation.

Agency form numbers, if applicable: HUD–52860.

Members of affected public: State, Local Government.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 120 respondents, on occasion, 16 hours average per response, 1,920 total reporting burden hours.

Status of the proposed information collection: Revision, new format.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: December 24, 1997.

Elinor Bacon,

Deputy Assistant Secretary for Public Housing Investments.

BILLING CODE 4210–33–M