(4) Notify the FDA liaison officer in writing of changes in acquisition regulations and practices which would affect the program covered by this MOU.

B. The Food and Drug Administration (FDA) agrees to:

(1) Furnish DPSC reports of complaint investigations.

(2) Upon request, provide pre-award quality evaluations for firms.

(3) Promptly advise DPSC when firms supplying medical products to DoD become unacceptable from a quality assurance standpoint.

(4) Determine the amount and nature of work it will perform to fulfill its responsibilities under this MOU.

(5) Make available FDA inspectional and analytical personnel as witnesses and supply information and data to DoD for GAO protests, Boards of Contract Appeals, SBA and similar cases.

(6) Review proposed specifications and provide comments on the quality assurance aspects.

(7) Notify the DPSC liaison officer in writing of changes arising from statutes or regulations which would affect this program.

(8) Promptly notify DPSC of product recalls and other pertinent information that affects government contracts or stocks.

(9) Advise DPSC of instances where fraud or other criminal conduct involving government contractors is found.

(10) Be responsible for determining that medical products offered for delivery were produced in accordance with the contract requirements, and for signing the acceptance document when source inspection is required.

(11) Conduct laboratory testing as necessary and, as expeditiously as possible, furnish DPSC analytical results. If testing cannot be accomplished, FDA will notify DPSC.

(12) Advise DPSC when FDA determines that it is necessary to convert a contract from destination to source inspection.

IV. Administration

A. Resources required to support this MOU will be provided by the performing party.

B. Nothing in this MOU will preclude DoD representatives from making visits to suppliers with FDA or separately.

C. The DPSC contracts for medical products will include a provision requiring compliance with the FDC and implementing regulations promulgated thereunder. The Good Manufacturing Practice Regulations will be the quality standard applied to industry for the manufacturing, processing, packaging or holding of medical products acquired on government contracts. The FDA will be the agency responsible for the administrative interpretation and enforcement of these statutes and regulations.

D. The DPSC may authorize the FDA to act as its agent for purposes of inspecting and accepting centrally acquired medical products, performance of preaward surveys, and related quality assurance actions.

E. As a general rule, the quality standards prescribed by the United States Pharmacopeia (USP), the National Formulary (NF), and FDA will satisfy the DoD quality requirements for products covered by the MOU; however, this does not preclude the development and utilization by DoD of additional standards when deemed essential to satisfy a unique or special requirement of DoD or any of the Military Services.

F. The FDA and DPSC, as necessary, will jointly prepare procedures covering operations that interface.

V. Participating Activity Liaison Officers

A. For the Department of Defense: Director, Medical Material, DPSC–M, Defense Personnel Support Center, Defense Logistics Agency, 2800 South 20th Street, Philadelphia, Pennsylvania 19101–8419, 215–737–2100.

B. For the Food and Drug Administration: Director, Medical Products Quality Assurance Staff, HFC–240, Office of Regulatory Affairs, Food and Drug Administration, 12720 Twinbrook Parkway, Bldg. #4, Room 408, Rockville, Maryland 20852, 301–827–0390.

VI. Period of Memorandum of Understanding

a. This MOU will become effective upon final signature and will remain in effect indefinitely.

b. The MOU will be reviewed every two (2) years to ensure adequacy and currency; however, it may be amended by mutual consent at any time.

c. The MOU may be unilaterally terminated by providing the other party with 180 days written notice of intent.

Approved and Accepted for the Department of Defense
By: Edward D. Martin, M.D.
Title: Principal Deputy Assistant Secretary of Defense, Health Affairs
Date: January 14, 1997

Approved and Accepted for the Food and Drug Administration
By: M. A. Friedman
Title: Deputy Commissioner for Operations
Date: November 27, 1996

[FR Doc. 97–21242 Filed 8-11-97; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0302]

Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Consumer-Directed Broadcast Advertisements.'' The draft guidance is intended to provide information to enable product sponsors to fulfill the requirements for consumer-directed broadcast advertisements, while providing consumers with required risk information about the advertised products. This draft guidance represents the agency's current thinking on consumer-directed broadcast advertisements for prescription drugs for humans and animals, and human biological products. The agency requests comments on this draft guidance.

DATES: Written comments may be submitted on the draft guidance document by October 14, 1997. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm 1–23, Rockville, MD 20857. Submit written requests for single copies of the draft guidance entitled ''Consumer-Directed Broadcast Advertisements'' 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 requests.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription human drugs: Nancy M. Ostrove, Division of Drug Marketing, Advertising and Communications (HFD–40), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, rm. 17B04, Rockville, MD 20857, 301–827–2828, or via e-mail at ostrove@cder.fda.gov.

Regarding prescription human 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 e-mail at stifano@cber.fda.gov.

Regarding prescription animal drugs: Edward Spenser, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD, 20855, 301–594–1722, or via e-mail at espenser@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Requirements

Section 502(n) (21 U.S.C. 352(n)) of the Federal Food, Drug, and Cosmetic

Act (the act) requires that advertisements for prescription drugs for humans and animals and human biological products include information in brief summary relating to side effects, contraindications, and effectiveness. This is known as the ''brief summary'' requirement. The prescription drug advertising regulations in § 202.1(e)(1) and (e)(3)(iii) (21 CFR 202.1(e)(1) and (e)(3)(iii)) further require that the brief summary disclose all the risk-related information in a product's approved package labeling (package insert or product package insert).

The regulations for advertising prescription drugs through broadcast media, such as radio, television, or telephone communications systems, however, modify the disclosure requirements somewhat. All prescription drug broadcast advertisements must include information about the major risks of the advertised drug (the ''major statement'') in either the audio or audio and visual parts of the presentation. Instead of presenting a ''brief summary'' in connection with the broadcast advertisement, a sponsor may make adequate provision for the dissemination of the approved package labeling in connection with the broadcast presentation (§ 202.1(e)(1)). This alternative requirement is referred to as the ''adequate provision'' requirement.

The ''adequate provision'' requirement recognizes the inability of broadcast advertisements of reasonable length to present and communicate effectively the extensive information that would be included in a brief summary; it instead specifies that presentation of the advertised product's most important risk information as part of the ''major statement,'' together with ''adequate provision'' for the dissemination of the approved labeling, can fulfill the risk information disclosure mandated by the act.

B. History

Although direct-to-consumer (DTC) advertising has been practiced by the prescription drug industry since the early 1980's, it has become increasingly popular in the 1990's. As a result, FDA has consulted recently with industry, consumers, health care professionals, and other interested parties regarding DTC prescription drug advertising.

In the **Federal Register** of August 16, 1995 (60 FR 42581), FDA published a document explaining the background of DTC promotion, asking for feedback on a number of DTC-related issues and questions, and announcing a public hearing regarding DTC promotion. The hearing was held on October 18 and 19, 1995, in Silver Spring, MD. In the **Federal Register** of May 14, 1996 (61 FR 24314), FDA published a followup document to address the erroneous belief expressed by some during the public hearing that FDA required preclearance of DTC promotion and to request feedback on several issues concerning DTC promotion. The notice clarified that FDA has never required DTC promotional materials to be precleared before use.

II. FDA's Plans Concerning Consumer-Directed Advertisements

As mentioned in section I.A of this document, the regulations addressing prescription drug and biological product advertisements are highly specific with regard to the kind and amount of information required to be disclosed or disseminated in connection with advertisements. Either a highly inclusive brief summary must be presented or, in the case of broadcast advertisements, substitution may be made by ensuring dissemination of approved package labeling. In response to recent agency requests for input, many comments have expressed concerns about the value for consumers of the complex, detailed information in the brief summary for print advertisements and approved package labeling for broadcast advertisements. FDA will initiate any rulemaking necessary to address these concerns. In the interim, FDA encourages product sponsors to provide consumers with nonpromotional, consumer-friendly information that is consistent with approved product labeling, in addition to the information currently required by the regulations (package insert for broadcast advertisements or brief summary for print advertisements). FDA suggests that this information follow the guidelines outlined in the ''Action Plan for the Provision of Useful Prescription Medicine Information'' coordinated by The Keystone Center, as accepted by the Secretary of the Department of Health and Human Services in January 1996. In cases where an advertised product has FDA-approved patient labeling, FDA encourages its inclusion as part of full prescribing information. In cases where the regulations require a brief summary, FDA encourages sponsors to write the brief summary in consumer-friendly language. This applies to consumer-directed print advertisements and broadcast advertisements that present a brief summary.

III. Consumer-Directed Broadcast Advertisements

Previously, FDA had not described how prescription drug and biological product sponsors could fulfill the ''adequate provision'' requirement for consumer-directed broadcast advertising. However, over the past several years, FDA has vastly expanded its experience in regulating DTC advertising that communicates important information and is not false or misleading. In light of the agency's increased experience and recent public input, FDA has reconsidered the issue of adequate provision as it relates to consumer-directed broadcast advertising. Therefore, FDA is publishing a draft guidance entitled, ''Consumer-Directed Broadcast Advertisements.'' It is directed to all new drug application, abbreviated new drug application, and abbreviated antibiotic drug application holders; biological product license holders; and new animal drug application and abbreviated new animal drug application holders. This draft guidance is intended to provide consumers with adequate communication of required risk information, while facilitating the process used by sponsors to advertise their products to consumers. This draft guidance describes an approach that sponsors can use to fulfill the requirement for adequate provision for dissemination of the approved package labeling in connection with consumer-directed broadcast advertisements for drug and biological products, as long as the advertisement itself includes a thorough major statement describing the product's most important risk information.

Within 2 years of publication of the final guidance, FDA intends to evaluate the effects of the guidance, including effects on the public health, of DTC promotion, and specifically of consumer-directed broadcast advertising. At the end of this evaluation period, FDA will determine whether this guidance should be withdrawn, continued, or modified to reflect the agency's current thinking. During this period, FDA will continue to collect information. The agency will keep the docket open to encourage the collection and submission of additional information from the public. FDA requests that sponsors and other interested parties collect relevant data on the impact of DTC promotional messages and make their findings known to the agency. FDA specifically solicits feedback on questions such as: (1) How has DTC promotion generally affected the public health; (2) to what

extent are consumers taking advantage of the mechanisms for obtaining approved package labeling in connection with broadcast advertisements; and (3) how risk messages can best be integrated into broadcast advertisements.

This draft guidance represents the agency's current thinking on procedures to fulfill the requirements for the disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human and animal drugs, and human biological products. 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 requirement of the applicable statute, regulations, or both.

IV. Request for Comments

Interested persons may, on or before October 14, 1997 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. An electronic version of this draft guidance is also available on the Internet at http://www.fda.gov/cder/guidance.htm.

Dated: August 5, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–21291 Filed 8–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (60 FR 56605 as amended November 6, 1995; as last amended at 62 FR 27613–16 dated May 20, 1997). This notice reflects the establishment of the HIV/AIDS Bureau and the Office of Special Programs.

The changes are as follows:

I. Delete the Bureau of Health Resources Development, and the AIDS Program Office (RAA), Office of the Administrator, in its entirety and replace with the following:

Section RV–00 Mission

The mission of the HIV/AIDS Bureau is to administer national policies and programs pertaining to HIV infection and acquired immune deficiency syndrome (AIDS) activities.

Section RV–10 Organization. The HIV/AIDS Bureau (HAB) is headed by an Associate Administrator who reports directly to the Administrator, HRSA. The (HAB) includes the following components:

(A) Associate Administrator for HIV/AIDS (RV)
(B) Office of Communications (RV1)
(C) Office of Program Support (RV2)
(D) Office of Policy and Program Development (RV3)
(E) Office of Science & Epidemiology (RV4)
(F) Division of Service Systems (RV5)
(G) Division of Community Based Programs (RV6)
(H) Division of Training and Technical Assistance (RV7)

Section RV–20 Function

A. Associate Administrator, HIV/AIDS Bureau (RV)

Provides leadership and direction for the Agency's HIV/AIDS programs and activities and oversees their relationship with other national health programs. Specifically: (1) Coordinates the formulation of an overall strategy and policy for HRSA AIDS programs; (2) coordinates the internal functions of the Bureau and its relationships with other national health programs; (3) establishes HIV/AIDS program objectives, alternatives, and policy positions consistent with legislation and broad Administration guidelines; (4) administers the Agency's HIV/AIDS grants and contracts programs; (5) reviews HIV/AIDS-related program activities to assure consistency with established policies; (6) represents the Agency and the Department at HIV/AIDS related meetings, conferences and task forces; (7) serves as principal contact and advisor to the Agency, Department, and other parties concerned with matters relating to planning and development of health delivery systems relating to HIV/AIDS; (8) develops and administers operating policies and procedures for the Bureau; (9) directs and coordinates the Bureau activities in support of the Department/Agency/Bureau's Affirmative Action and Equal Employment Opportunity programs by ensuring that all internal employment practices provide an equal opportunity to all qualified persons and its employment practices do not discriminate on the basis of race, color, sex, age, handicapping conditions, national origin, religious or political affiliation, marital status, and that all external benefits and service oriented activities relative to the recipients of Federal funds are likewise addressed in accordance with applicable laws, Executive Orders, DHHS regulations and policies; and (10) provides direction to the Bureau's Civil Rights compliance activities.

B. Office of Communications (RV1)

The Office of Communications serves as the Bureau's clearinghouse on all HIV/AIDS grant and program data and information, directing, coordinating and managing the preparation and dissemination of newsletters, program profiles, and reports on the uses of grant funds and services provided. Specifically: (1) Collects, compiles, and distributes various data and information on HIV/AIDS health care issues and programs related to the activities of the Bureau; (2) develops and provides information materials to HIV/AIDS health program planners, providers, and consumers to assist in decisionmaking and in effective, efficient operations; (3) develops and produces in-house communications to help ensure the understanding of current AIDS issues and Bureau program activities; (4) maintains information about primary sources of data and information on the health industry, disease trends, and public and private programs; (5) fosters and maintains relationships with and provides a referral service to Federal agencies, State and local governmental units, and private health and medical organizations with which the Bureau has mutual interests; (6) provides technical assistance to Bureau program managers and project officers in identifying data and information needs and developing information products; (7) provides technical assistance to Bureau program managers in information and communications product packaging, desktop publishing, and media relations; (8) provides Bureau liaison with HRSA's Office of Communications with respect to information and communications policy and management, product development, and media relations; (9) produces reports, articles, briefings, speeches, and exhibits on Bureau services and on programs directed at the Bureau service and provider populations; and, (10) utilizes automated methods and electronic media in carrying out its