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Guidance for Industry

Consumer-Directed Broadcast Advertisements

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*. Regarding prescription animal drugs contact 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.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
August 1997

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U.S. Department of Health and Human Services
Food and Drug Administration
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July 1997

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GUIDANCE FOR INDUSTRY[1]

CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS

I. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors ("sponsors") who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs, the Act requires advertisements to contain "information in brief summary relating to side effects, contraindications, and effectiveness" (21 U.S.C. 352(n)). The resulting information disclosure is commonly called the "brief summary."

The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the "major statement." This guidance does not affect the major statement requirement in any way.

In addition, sponsors of broadcast advertisements may present a brief summary or, alternatively, may make "adequate provision ... for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (21 CFR 202.1(e)(1)). This alternative requirement is referred to as the "adequate provision" requirement. The regulations thus specify that the major statement, together with adequate provision for dissemination of the product's approved labeling, can provide the information disclosure required for broadcast advertisements.

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement for "adequate provision" in connection with consumer-directed broadcast advertisements for prescription drug and biological products, assuming that the advertisement contains a thorough "major statement" describing all of the product's most important risk information.

II. FULFILLING THE "ADEQUATE PROVISION" REQUIREMENT FOR PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS

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[1]This guidance has been prepared by the Intra-Agency Working Group on Advertising and Promotion at the Food and Drug Administration. This 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.

Any set of procedures used to fulfill the "adequate provision" requirement in consumer-directed broadcast advertisements for prescription drug and biological products presumes that the advertisement itself includes a thorough "major statement" conveying all of the product's most important risk information. This approach also assumes that all information relevant to the product's indication (including limitations to use) is communicated in consumer-friendly language, and that the advertisement is not false or misleading in any respect.

Given these presumptions, a sponsor wishing to use consumer-directed broadcast advertisements may meet the adequate provision requirement by providing an effective mechanism by which the majority of a potentially diverse audience can receive the advertised product's approved labeling. This audience is likely to include persons with limited access to technologically sophisticated outlets (e.g., those without access to the Internet or personal fax machines) and persons who hesitate to actively request or receive additional product information. One acceptable mechanism is described below. It includes providing the following four components:

A. Including in the advertisement an operating toll-free telephone number for consumers to call for the approved package labeling. Upon calling, consumers should be given the choice of:

- having the labeling mailed to them in a timely manner (e.g., within 2 business days for receipt generally within 4-6 days);
- having the labeling faxed to them in a timely manner (e.g., upon completion of the call or within the next few hours); or,
- having the labeling read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics).

B. A mechanism to obtain package labeling for consumers with restricted access to sophisticated technology, such as the Internet, as well as those who are not active information seekers. One acceptable mechanism would be to state in the broadcast advertisement that additional product information is provided with print advertisements appearing concurrently in publications that reach the exposed audience. As is required for consumer-directed print advertisements, these referenced advertisements would provide both risk information in the advertisement's text and a "brief summary." If a print advertisement is part of a set of adequate provision procedures, as in the example given here, the advertisement also should supply a toll-free telephone number and/or address for further consumer access to the full package labeling.

An alternative mechanism would be to provide sufficient numbers of brochures containing package labeling in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries). Brochures should be available at enough sites so that most consumers exposed to the broadcast advertisement can obtain the labeling without

traveling beyond their normal range of activities.

C. A statement in the broadcast advertisement that pharmacists, and/or physicians, and/or veterinarians (in the case of animal drugs) may provide additional product information to consumers.

D. An Internet web page (URL) address in the broadcast advertisement or via the associated toll-free telephone number contact that provides access to the package labeling.

Although current broadcast advertising regulations require that the approved package labeling be provided, the Agency encourages sponsors to provide consumers with nonpromotional, consumer-friendly product information as well (e.g., FDA-approved patient labeling).

To enable the agency to evaluate the effects of this guidance, FDA requests that sponsors who use this "adequate provision" mechanism collect relevant data and make their findings known to the agency.