

Draft Guidance for Industry and FDA

**Consumer-Directed Broadcast
Advertising of Restricted Devices**

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document contact Deborah Wolf, 301-594-4595, ext. 171 or daw@cdrh.fda.gov

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Office of Compliance

Contains Nonbinding Recommendations

Draft -- Not for Implementation

Preface

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Consumer-Directed Broadcast Advertising of Restricted Devices

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance is intended to assist manufacturers, packers, and distributors (sponsors) who are interested in advertising their restricted devices directly to consumers through broadcast media, such as television, radio, or telephone communication systems.¹

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

¹ This guidance is intended to cover devices that have been designated by FDA as "restricted," either by regulation promulgated under section 520(e) of the Act (21 U.S.C. 360j(e)), or by premarket approval application (PMA) approval order pursuant to section 515(d)(1)(B)(ii) (21 U.S.C. 360e(d)(1)(B)(ii)).

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Background

The Federal Food, Drug, and Cosmetic Act (the Act) requires that manufacturers, packers, and distributors who advertise restricted devices distributed or offered for sale in any State include in all advertisements certain information about the advertised device's uses and risks. Specifically, the Act requires such advertisements to contain "a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications" (21 U.S.C. 352(r)(2)) (brief statement).

The purpose of this guidance is to describe an approach that FDA believes can fulfill the requirement of the brief statement in connection with consumer-directed broadcast advertisements for restricted devices. The approach presumes that such advertisements:

- Are not false or misleading in any respect.² This would include communicating that the advertised device is restricted to sale, distribution, or use only upon authorization of a licensed practitioner or upon other conditions established by FDA in regulations or in an approval order.
- Present information about effectiveness and information about risk in a balanced manner.
- Include a thorough major statement conveying all of the device's most important warnings, precautions, side effects, and contraindications in consumer-friendly language.
- Communicate all information relevant to the device's indication (including a brief statement of the intended use(s) of the device and any limitations to use) in consumer-friendly language.

²Under section 502(q) of the Act (21 U.S.C. 352(q)), a restricted device is misbranded if its advertising is false or misleading in any particular.

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Fulfilling the Brief Statement Requirement

A sponsor wishing to use consumer-directed broadcast advertisements may meet the brief statement requirement through an approach that: (1) discloses the most serious and the most common risks associated with the device in either the audio or audio and visual parts of the presentation; and (2) makes adequate provision for dissemination of the approved or permitted package labeling³ in connection with the broadcast presentation.⁴ A consumer-directed broadcast advertisement makes adequate provision within the meaning of this guidance if it will allow most of a potentially diverse audience to have reasonably convenient access to the advertised device's labeling. This audience will include many persons with limited access to technologically sophisticated outlets (e.g., the Internet) and persons who are uncomfortable actively requesting additional device information or are concerned about being personally identified in their search for device information. One acceptable approach to disseminating the device's labeling is described below. This approach includes the following components.

A. Disclosure in the advertisement of 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); or
- Having the labeling read to them over the phone (e.g., by offering consumers a selection of prerecorded labeling topics).

B. Reference in the advertisement to a mechanism to provide package labeling to consumers with restricted access to sophisticated technology, such as the Internet, and those who are uncomfortable actively requesting additional device information or are concerned about being personally identified in their search for device information. One acceptable mechanism would be to provide the additional device information in the form

³ Package labeling for many medical devices is extensive and includes highly technical and professional procedural information (e.g., maintenance sections and detailed operative procedures) that may not be helpful to the consumer in deciding whether to discuss the device further with a healthcare professional. FDA recommends that sponsors of such devices develop patient labeling, if possible. An abbreviated version of the package labeling containing information on indications, contraindications, warnings, precautions, and adverse effects, and patient instructions for use may be extracted and disseminated instead of the full package labeling, provided the consumer is informed that the abbreviated version is not the full package labeling. For more information on patient labeling, see CDRH's "Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA" (<http://www.fda.gov/cdrh/ohip.guidance/1128.html>).

⁴ FDA recommends that consumer-directed advertisements for hearing aids make adequate provision for dissemination of the User Instructional Brochure in connection with the broadcast presentation. This guidance is not intended to affect the requirements that the User Instructional Brochure accompany a hearing aid (21 CFR 801.420(c)) or that the Brochure be provided to a prospective purchaser of a hearing aid (21 CFR 801.421(c)).

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of print advertisements appearing concurrently in publications that reach the exposed audience. The location of at least one of these advertisements should be referenced in the broadcast advertisement. If a print advertisement is part of a brief statement procedure, it should supply a toll-free telephone number and an address for further consumer access to full package labeling.

When a broadcast advertisement is broadly disseminated, FDA believes that ensuring that passive and privacy-sensitive information seekers have adequate access to detailed device information is critical to complying with the brief statement requirement. Thus, print advertisements associated with broadly disseminated broadcast advertisements should be comparably broadly disseminated in terms of the targeted audiences.

An alternative mechanism for providing private access to device information would be to ensure the availability of 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. This alternative mechanism is likely to be logistically feasible only when the associated broadcast advertising campaign is relatively limited in audience reach.

C. Disclosure in the advertisement of an Internet web page (URL) address that provides access to the package labeling.

D. Disclosure in the advertisement that practitioners may provide additional device information to consumers. This statement should communicate clearly that the referenced professional is a source of additional device information.

Telephone advertisements that make a device claim occur when there is a telephone communication between an individual and a device's sponsor where both a device name and a representation or suggestion relating to a device (e.g., its indication) are disclosed by the sponsor. Under these circumstances, such advertisements are subject to the requirements of section 502(r) of the Act. However, telephone advertisements are different from advertisements broadcast through television and radio. By participating in the telephone communication, the consumer has already indicated his or her willingness to discuss the topic or receive additional information. Consequently, compliance with the brief statement requirement may be achieved with fewer of the components listed above. For such advertisements, the brief statement could consist of the availability of the option of having device labeling mailed to the caller in a timely manner (e.g., within 2 business days for received generally within 4-6 days), or having the labeling read to them over the phone (e.g., by allowing consumers to select from prerecorded labeling topics), as well as disclosing that healthcare providers are a source of additional device information.

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When a broadcast advertisement is presented in a foreign language, the information sources that are part of the advertisement's brief statement (i.e., print advertisements or brochures, web sites toll-free telephone number recorded messages or operators) should be in the language of the broadcast ad. Regardless of the language used for the advertisement, FDA strongly encourages sponsors to consider the benefits of providing consumers with nonpromotional, consumer-friendly device information in the language of the broadcast ad (e.g., FDA-approved patient labeling or accurate, consumer-friendly translations of device labeling information).

The FDA encourages sponsors who use this approach to satisfy the brief statement requirement of section 502(r) to collect relevant data on consumer use and make their findings publicly known. FDA also encourages sponsors and other interested parties to make known their research relating to the overall effects of DTC promotion on the public health.

Guidance for Industry

Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

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For questions regarding this draft document, contact (CDER) Lesley R. Frank at 301-827-2831 or (CBER) Glenn Byrd at 301-827-3028.

**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)**

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