Guidance for Industry
Consumer-Directed Broadcast Advertisements
Questions and Answers

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Consumer-Directed Broadcast Advertisements Guidance Questions and Answers[1]

Q: What are the differences, if any, between the draft guidance and the final guidance concerning consumer-directed (direct-to-consumer or DTC) broadcast advertisements?

A: The final guidance does not differ substantially from the draft guidance. Minor revisions include: (1) reformatting the assumptions underlying what constitutes a compliant broadcast advertisement in general; (2) deleting the option under the toll-free telephone component of the adequate provision approach to offer to fax product labeling to consumers; (3) emphasizing the need for the print advertisement component of the adequate provision approach to be broadly disseminated; (4) acknowledging that the print brochures alternative component of the adequate provision approach was likely to be feasible only when broadcasting was fairly limited in scope; (5) acknowledging explicitly that healthcare providers other than physicians and pharmacists can be sources of additional human drug product information; and (6) adding a discussion to clarify the differences in satisfactory adequate provision approaches for telephone advertisements, compared with television or radio advertisements.

Q: In the draft guidance, FDA described four components of its suggested multifaceted approach to complying with the adequate provision requirement. What is FDA's position in the final guidance about whether all the different sources from which consumers can get theproduct labeling need to be included to ensure an acceptable adequate provision approach?

A: The approach to adequate provision discussed in the draft guidance included disclosure of four sources of product labeling information: (1) a toll-free telephone number; (2) referral to a print advertisement in a concurrently running print publication, or provision of enough brochures, with required product information, in various convenient outlets; (3) referral to a healthcare provider (physician, pharmacist, veterinarian); and (4) an Internet web page address. Some comments on the draft guidance expressed the general concern that there was insufficient flexibility in the proposed approach, and felt that product sponsors should be allowed to determine on a product by product basis the components of adequate provision to include in a broadcast advertisement. For the following reasons, FDA continues to believe that a multifaceted approach is the best approach and that,

ordinarily, all four sources should be used.

The approach proposed in the draft guidance was one that the Agency believed could help ensure adequate access to the advertised product's labeling by most of a diverse audience with different information-seeking styles. Targeted audiences are likely to consist of individuals with different degrees of technological sophistication or access to technologically sophisticated information sources (like the Internet), with different information-seeking styles, and with different levels of concern about privacy and how they receive potentially sensitive information. Adequate provision requires that this broad audience be able to receive the detailed information.

When FDA issued the draft guidance, it also requested information from manufacturers and other interested parties concerning consumer use of the four sources of additional information. No evidence was submitted by manufacturers supporting contentions that any of the four information sources were underutilized, or that there was significant overlap in usage. In fact, the results of recent consumer survey research conducted by both Prevention magazine and TIME Inc. supports FDA's belief that different sourceswould be used by different individuals in seeking out additional product information on seeing a broadcast advertisement. The most commonly used source of additional information about the product appears to be the consumer's healthcare provider. The other information sources were used by lower, although approximately equal, percentages of consumers. The only significant overlap appears to occur when patients consult with a health professional and also use one of the other three information sources.

The research also suggests, however, that although the toll-free number and referral to a health professional are being communicated effectively, the web page address, and, to an even greater degree the print reference, are not. Relatively low percentages of consumers in the Prevention survey who had seen prescription drug broadcast advertisements said that they remembered a print or Internet address reference. In contrast, a clear majority of respondents reported recalling the reference to a healthcare professional and a toll-free number. The most likely explanation is that the advertisements themselves are inadequately presenting the web page address and reference to print sources. Even a cursory examination of existing broadcast advertisements shows that the toll-free telephone number is on screen for far longer than either the print or web page disclosures. FDA continues to believe that a multifaceted approach will best ensure adequate dissemination of product labeling. Moreover, sponsors of broadcast advertisements for prescription products should present references to the different information sources in a more balanced fashion.

FDA believes that it is critical to have additional product information available in print, especially for audience members who are particularly sensitive to privacy issues in seeking out additional information. Supportive data from the TIME, Inc. survey indicated that about half of consumers say it is either extremely or very important for DTC advertising to be able to be reviewed privately to avoid embarrassment. Given this, it is important that these sources of information be prominent and widely available. A display ad with graphics is more likely to be easily found than straight text when presented in a magazineor newspaper format. FDA therefore recommends that sponsors consider the enhanced value for consumers of including more than just a brief summary and a 1-800 number in print advertisements that are part of adequate provision.

Q: What does the final guidance say about the alternative to the print advertisement component of adequate provision of making brochures available in many different convenient locations?

A: The draft guidance offered an alternative to referencing a print advertisement as part of adequate provision. The alternative was to provide brochures with full product information in a variety of convenient, publicly accessible sites, such as pharmacies, doctors' offices, grocery stores, and public libraries. A concern with this method expressed by some comments was that it would be difficult to ensure the availability of enough of the brochures in sites outside the control of the advertised product's sponsor. Another comment was that such brochures should only be made available at doctors' offices and pharmacies. The Agency agrees that the provision of sufficient brochures for a national broadcast audience might be difficult, but decided to retain the alternative because it could be a useful option in some cases (e.g., under certain relatively limited broadcasting circumstances). FDA believes, however, that limiting distribution to doctors' offices and pharmacies would defeat the purpose of this component, which is to help ensure widespread access to product information for people who may be uncomfortable with being personally identifiable, including those uncomfortable having their initial information searches

take place in medical care arenas.

Q: I've seen references in prescription drug broadcast advertisements to print ads for the product in very targeted, relatively limited availability magazines. How well does this practice fulfill the adequate provision requirement?

A: In monitoring various broadcast advertisements since the draft guidance was issued forcomment in August 1997, FDA has noted wide variability in the print publications used to fulfill this component of adequate provision. FDA has also received data indicating wide variability in the likelihood of exposure of consumers to associated print advertisements. Some sponsors' approaches to this component of adequate provision have included publication in, and reference in their broadcast advertisements to, magazines with relatively wide circulation and availability. For some products advertised on TV and radio, print advertisements have appeared in multiple magazines, increasing the likelihood that passive information seekers will be exposed to additional product information. Other sponsors, in contrast, have published advertisements solely in infrequently published or limited distribution magazines that are unlikely to be available in places such as newsstands and grocery stores for more than a week during the period of a month or two that the broadcast advertisement is airing. This practice greatly decreases the likelihood that passive information seekers will be exposed to product information and that information seekers concerned about their privacy will be able to find such information.

> FDA generally believes that a sponsor has not provided adequate access to the product's package labeling when the print component of their adequate provision approach is highly targeted or made only narrowly available and the product is broadly advertised in broadcast media. FDA intends to monitor the availability of print advertisements to passive and privacy-sensitive information seekers, when such advertisements are part of an adequate provision approach. In doing so, FDA may request that sponsors provide information on the availability of this component. Such requests could include information about reach, frequency, and total number of exposures of both the broadcast and associated print advertisements.

Q: At meetings, I've heard about data that suggest that not many broadcast ad viewers ask to have product labeling sent to them by facsimile. Given this, why does FDA include faxing the labeling as part of its adequate provision approach?

A: Specific comments made concerning the draft guidance pointed to the logistically cumbersome nature of ensuring the delivery of faxes resulting from calls made to the toll-free telephone number. In addition, FDA notes that data from more than one product manufacturer indicate that only a small percentage of callers request that product labeling be faxed to them. FDA also believes that individuals who own a fax machine are likely to have convenient access to the Internet. Given that the Agency has no wish to burden sponsors unnecessarily by encouraging overlapping availability of labeling through different technologically sophisticated means, the Agency has reconsidered its position with regard to faxes and revised the guidance to delete the suggestion that consumers calling the toll-free telephone number be offered the option of having product labeling faxed to them.

Q: The draft guidance included the mechanism of having package insert information read to consumers through the toll-free telephone number. Do consumers use this and is it really necessary?

A: Limited data from at least one manufacturer, as well as additional anecdotal reports, suggest that a significant percentage of callers ask to have product information read to them. Therefore, FDA kept this option in the final guidance. Once consumers gain experience with the mechanism, it is conceivable that such requests to have PI information read will decrease significantly. If it appears that people are not using this mechanism, we are prepared to revise the guidance.

Q: What about DTC prescription drug advertising in general? Aren't there a lot of negative effects associated with it? Isn't FDA interested in these?

A: A number of comments asserted that the draft guidance was inappropriate because of postulated negative effects associated with consumer-directed prescription drug advertisements in general. These comments generally asserted that FDA was shirking itsresponsibility to the public health by allowing any DTC advertising, and was exacerbating the ill effects of prior actions concerning DTC promotion by inappropriately loosening restrictions on broadcast advertisements.

FDA is unaware of any data supporting the assertion that the public health or animal health is being harmed, or is likely to be harmed, by the Agency's actions in facilitating consumer-directed broadcast advertising. FDA has repeatedly requested empirical data that would document the hypothesized effects - negative and positive - of DTC promotion on several factors related to public health. Despite years of print DTC advertising, no rigorous evidence has been presented to demonstrate that DTC advertising has had any of the hypothesized ill effects. In the absence of such data, FDA believed that the advantages of having a broadcast environment that would encourage communication of both the benefits and the risks of advertised products outweighed the postulated, but never demonstrated, disadvantages. In issuing the draft guidance, FDA again asked that research be conducted to document the effects of DTC promotion on the public health and animal health and specified that it would conduct an evaluation of such effects within 2 years of finalizing the guidance.

FDA does not agree that it has loosened restrictions on broadcast advertisements, although we have taken steps to make them more feasible. Since being promulgated in the 1960s, the regulations have provided for alternative requirements for broadcast, as compared with print, advertisements. Although product sponsors theoretically had the option of using the adequate provision alternative instead of presenting a brief summary in connection with broadcast advertisements, the absence of formal guidance created uncertainty about how the Agency would treat any particular approach. The result was a broadcast environment confusing to consumers and less than optimal for effectively communicating product information. Given that there are no legal impediments to such consumer-directed broadcast advertising, the Agency was obliged to provide appropriate guidance.

***Q: The draft guidance emphasized the underlying regulatory assumption about broadcast advertisements that they must contain disclosure of all of the most important risks associated with the product. Can this really be done in consumer-directed broadcast advertisements*?**

A: A basic regulatory requirement for any broadcast advertisement is that it include a thorough major statement conveying all of the product's most important risk information. Some comments asserted that the limited duration of a broadcast advertisement would not permit adequate presentation of potential risks or an adequate risk/benefit discussion. FDA believes that risk information can be adequately communicated in a broadcast advertisement. Since the draft guidance was issued for comment in August 1997, many product sponsors have produced broadcast advertisements that FDA believes satisfactorily disclose the most important risk information about the advertised products. In some cases, FDA has objected to the initial content or presentation of risk disclosure, but in virtually all of these cases, the sponsor was able to revise the advertisements to address FDA's concerns. Success in presenting risk information may reflect the choice of products for broadcast DTC promotion; many have been drugs without major risks. It may be that sponsors are reluctant to promote products with serious risks to consumers in a broadcast format.

Some comments asserted that there should be no risks or only general risks disclosed in broadcast advertisements. The regulations, however, provide only limited flexibility for risk disclosure in broadcast advertisements. The regulations specify that such ads must include information relating to the product's major risks ("major side effects and contraindications") in addition to providing either a brief summary or adequate provision for disseminating full product labeling. More significantly, the Federal Food, Drug, and Cosmetic Act (the act) specifies clearly that advertisements must contain "information in brief summary relating to side effects, contraindications, and effectiveness" of the advertised drug (21 U.S.C. 352(n)). FDA believes that the clarity of the statute on this matter precludes permitting such advertisements to omit product risks completely. Inaddition, FDA believes that the benefits and risks of drugs are specific, not general, and that even though the prescribing decision ultimately will be made by the patient's healthcare provider, a patient's decision to discuss with his or her provider the possibility of getting a prescription for the advertised product should be shaped by at least a general understanding of the product's benefit(s) and risk(s). This also helps assure that these risks will be part of the discussion. The Agency notes that DTC broadcast promotion cannot possibly contain information sufficient for even a medically trained person to make an informed decision about use of the product, much less a person without such training. The decision to use a prescription drug requires a consultation between the patient and a healthcare provider familiar with the entire product labeling.

Q: What about the requirement for disclosure of product information (e.g., product labeling, brief summary) that is generally not written for consumers? Can't it be written so consumers can understand it?

A: FDA acknowledges that product labeling generally is written for healthcare professionals. However, the number of *Physicians' Desk References* sold to consumers attests to the value many consumers place on medical product labeling information. In addition, the regulations are straightforward in specifying that "approved or permitted" package labeling be disseminated in connection with broadcast advertisements. However, the guidance encourages sponsors to consider the benefits of also providing consumers with nonpromotional, consumer friendly product information. The Agency notes that it is currently evaluating the regulations as they relate to DTC print promotion and will address this issue in greater detail at a later date.

> In addition, FDA has consistently noted that the brief summary required for prescription drug advertisements does not need to consist of a reprinting of the risk-related sections of product labeling, and can be written in light of the target audience, as long as all the risk concepts are addressed. Finally, the Agency reiterates that if patients do not understandall of the information in brief summaries or labeling, their prescriber can answer any questions they may have.

Q: I've noticed that there are consumer-directed broadcast advertisements that are in Spanish. What's the required information in this case and how does the sponsor ensure that the audience for these ads have access to this information?

A: When an advertisement is clearly directed toward an audience that speaks a foreign language, it is critical that the information sources that are part of the "adequate provision" mechanism be understood by the targeted audience. Therefore, the various sources of product information (i.e., the toll-free telephone number, print advertisement, web site) should be in the language of the advertisement. This would provide the necessary link to the required information. The regulations require dissemination of approved product labeling, which generally must be in English. However, the Agency strongly encourages sponsors to consider the benefits of also providing foreign language speaking consumers with nonpromotional, consumer-friendly product information in the language of the broadcast advertisement.

Q: Can't healthcare professionals other than physicians write out prescriptions for these medications? Some broadcast ads seem to suggest that only physicians can prescribe certain medications.

A: There is a difference between human drugs and animal drugs with respect to prescribing authority. Only veterinarians can prescribe animal drugs. However, for human drugs, prescribing authority is determined by state law. In some states, healthcare professionals other than physicians can prescribe human drugs. FDA notes that the inclusion of pharmacists as part of the suggested mechanism for achieving adequate provision clearly indicates that healthcare professionals other than physicians are sources of additional product information. Because FDA does not wish to undermine the importantcontribution of various healthcare professions, it revised the guidance to suggest that the term *other healthcare providers* may be used in the referenced adequate provision component. FDA also reminds sponsors of prescription drug advertisements to be careful not to imply that only physicians can prescribe their products.

Q: It seems as though the risk information that's included in DTC broadcast advertisements is often being read at the same time that there is information disclosed in the video part of the advertisement about the components of the adequate provision procedure. Is this a potential problem for the communication of both types of information?

A: FDA previously solicited research on such questions as how best to integrate risk messages into broadcast advertisements. This question is of special concern given the television advertisements that have aired since the draft guidance was issued. Since August 1997, television advertisements have appeared for over 25 prescription animal or human drug products. For a number of these advertisements, FDA noted through letters to various product sponsors that the disclosure of risk information was deficient in one way or another. Many of these objections were based on the presentation of distracting visual images in the background during the required audio disclosure of the advertised product's major risks. The Agency was concerned that such distractions interfered with the adequate communication of required risk information. In addition, in at least two cases, FDA has determined that advertisements were violative because information about different risks was simultaneously

presented in the audio and visual parts of the presentation, making both topics unlikely to be adequately comprehended or processed. To date, FDA has not objected to video presentation of the adequate provision disclosures simultaneously with the required audio presentation of the risk information (generally by a *voice over*). Historically, FDA has believed that the simple processing needed to notice, read, comprehend, and process adequate provision video disclosures would not interfere with the processing of risk information presented in the audio. However, given the data mentioned previously showing low recall of the print and web page disclosures, FDA isbecoming concerned that this common practice may interfere with the communication of critical risk information or with the simultaneous disclosure of the adequate provision components. Consequently, FDA will be examining this question very carefully within the 2-year evaluation period. FDA specifically solicits the submission of empirical data concerning this question.

1 These questions and answers on the Consumer-Directed Broadcast Advertisements guidance have been prepared by the Intra-Agency Group on Advertising and Promotion at the Food and Drug Administration. They represent the Agency's current thinking on procedures to fulfill the requirements for disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human and animal drugs, and human biological products. They do not create or confer any rights for or on any person and do 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.

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