Comments Related to Required Report on Direct-to-Consumer Advertising
[Docket No. FDA-2008-N-0226]

The Food and Drug Administration (FDA) is requesting scientific research, data and information that would assist the agency in its plans to conduct an assessment of direct-to-consumer (DTC) advertising and its ability to communicate to subsets of the general population, including the elderly, children, and racial and ethnic minority communities. The agency is taking this action to comply with section 901 of the Food and Drug Administration Amendments Act of 2007 (Pub. Law 110-85) (FDAAA), which mandates that the agency report to Congress on DTC advertising's effect on increased access to health information and decreased health disparities for these populations. The agency's report to Congress must include recommendations on how to effectively present and disseminate information to these groups.

FDAAA mandates that FDA utilize the Advisory Committee on Risk Communication to advise the agency with respect to this report. On May 15, 2008, the committee will meet for presentations and discussion of the topics outlined above. FDA asks that interested parties submit comments on these topics to this docket [Docket No. FDA-2008-N-0226]. Submit electronic comments and information to http://www.regulations.gov. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments are to be identified with the docket number in brackets above, and will be posted without change, including any personal information provided. Submissions received to this docket on or before May 8, 2008, will be provided to the committee before or at the meeting; submissions received after that time but before September 27, 2008 will still be considered in preparing the report for Congress.

FDA is particularly interested in scientific research, data and information on the topics outlined in the following paragraphs.

1. Are different subsets of the population in the United States, including the elderly, children, and racial and ethnic minority communities, being targeted or reached by DTC promotion? If so, which segments of the population and to what extent?

2. Furthermore, if any subsets of the population such as the elderly, children, and racial and ethnic minority communities are being reached or targeted by DTC promotion, what effect, if any, does this DTC promotion have on its intended audience?

   a. For example, FDA is interested in scientific data that relates to the existence of a relationship between targeted DTC promotion and the disease or condition at issue. For example, was the targeted audience particularly appropriate for the drug being promoted (e.g., high prevalence of the disease the drug treats in the audience)?
   b. FDA also is interested in receiving data as to whether DTC promotion is providing educational content about the diseases or conditions at issue. If so, is this educational content sufficient or should additional educational content about the disease or condition be provided?

c. Moreover, FDA is interested in any data that relates to any type of relationship between targeted DTC promotion and subsequent contact (telephonic, e-mail, office or clinic visit) with a health care provider by the targeted consumer. If there is a relationship between exposure to the promotion and contact with a health care provider, how soon after the targeted audience is first exposed to the advertisement does this contact occur?

d. Furthermore, FDA is interested in scientific data that relates to an actual improvement in health as a result of the targeted promotion. For example, after being exposed to the promotion, did the targeted audience engage in behavior modification (i.e. exercise, diet) that was directed at improving health?

e. Finally, FDA is interested in any data that relates to difficulties a targeted audience had in understanding the content in a DTC ad about a disease or condition. Are there any segments of the population for which targeted DTC promotion resulted in behavior that was unintended or unforeseen? If so, what type of behavior and to what extent?

3. Are there any subsets of the population for which targeted DTC promotion should generally be deemed to be inappropriate? If so, which subsets of the population and why? Furthermore, if there are such subsets of the population, are there any best practice approaches that the FDA should consider with respect to these population subsets?

4. Are there any advertising strategies that raise concern when such strategies are applied to prescription drug advertisements that are directed to specific subsets of the population? Conversely, are there any advertising strategies that reflect an approach to promotion that the data indicates should be used with respect to advertisements directed to a certain subset of the population?