DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Frederick S. Mayer, R.Ph., M.P.H.
Pharmacists Planning Service, Inc.
101 Lucas Valley Road
Suite 210
San Rafael, CA 94903

Re: Docket Number: FDA-2007-P-0413

Dear Mr. Mayer,

This letter responds to your citizen petition dated February 14, 2007 (Petition),[1] requesting that the Food and Drug Administration (FDA or Agency) standardize and increase the print size for direct-to-consumer (DTC) advertising of prescription drug products, over-the-counter (OTC) drug products, and herbal products[2] to enhance their readability.

After careful consideration of your petition and submitted materials, we deny your request for the reasons discussed below.

I. BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act[3] (FD&C Act), FDA is responsible for regulating the advertising of prescription drugs. As described below, since 1985 FDA has applied the FD&C Act and the prescription drug advertising regulations[4] to both professional and consumer-directed promotion. Although the FD&C Act does not distinguish between consumer and professional audiences in its requirement for disclosure of relevant risk information in prescription drug advertising, FDA recognizes and accounts for the differences between healthcare professionals and consumers as recipients of drug promotion, including differences in medical and pharmaceutical expertise, perception of pharmaceutical claims, and information processing. FDA

[1] This citizen petition was originally assigned docket number 2007P-0065/CP1. The number was changed to FDA-2007-P-0413 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] Although not clearly stated in your petition, we presume that your request to increase the print size for DTC advertising refers specifically to the "brief summary" that is required to accompany a DTC print advertisement. The brief summary requirement is discussed in Section I of this response. There are no brief summary requirements for advertised OTC or herbal products. Moreover, although FDA maintains primary jurisdiction over product labeling for OTC and herbal products, the Federal Trade Commission maintains primary jurisdiction over advertising matters associated with those products. These generally address untruthful or misleading claims, issues outside the scope of your petition. This response, therefore, addresses your readability request for brief summaries associated with prescription drug DTC print advertisements.

[3] 21 U.S.C. 301 et seq.

[4] 21 CFR Part 202.

reviews DTC prescription drug advertisements to help ensure that the information is not misleading and that contextual information for benefits and risks is presented, while encouraging sponsors to provide such information in language understandable to consumers.

Under section 502(n) of the FD&C Act (21 U.S.C. 352(n)), an advertisement for a prescription drug must contain, in addition to the product's established name and quantitative composition, a "true statement" of "such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations. . . ." This requirement is further defined in the prescription drug advertising regulations at 21 CFR 202.1(e)(1), which require that an advertisement contain a "true statement of information in brief summary relating to side effects, contraindications . . . and effectiveness." Under 21 CFR 202.1(e)(3)(iii), "The information relating to side effects and contraindications shall disclose each specific side effect and contraindication (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc. . . .) contained in required, approved, or permitted labeling for the advertised drug dosage form(s)." The requirement that an advertisement for a prescription drug disclose each side effect, warning, precaution, and contraindication from the required, approved, or permitted labeling is known as the *brief summary* requirement.

To fulfill the brief summary requirement, consumer-directed print advertisements for prescription drugs include information from the risk-related sections of approved professional labeling. In the past, many manufacturers reprinted *all* of the risk-related sections of the approved professional labeling to fulfill the brief summary requirement. However, the January 2004 draft guidance for industry *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* recommends against reprinting the complete risk-related sections of the approved professional labeling and against using small print size in the brief summary in consumer directed print advertisements.[5] This draft guidance further provides examples of formats that present pertinent risk information in a readable format.

II. DISCUSSION

Your petition request that FDA issue a Federal regulation to increase print size of DTC advertising is based primarily on the occurrence of print size in drug advertisements (i.e., brief summaries) contained in newspapers and magazines that are too small for consumers and patients to read (Petition at 1). You provided several examples of these occurrences that appear in consumer and healthcare professional advertisements.

We believe that you raise valid points about the importance of readability of the brief summary in prescription drug DTC advertisements. We share your concern that this

[5] This draft guidance is available online at http:// http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm. When finalized, it will represent FDA's current thinking on the topics it covers.

important information should be presented in such a way that it can be read and understood, in accordance with the FD&C Act and FDA regulations.

However, after careful consideration of the information you have provided in the Petition, we have determined that it is not necessary or appropriate to revise our regulations at this time. We already have sufficient legal authority to take action under section 502(n) of the FD&C Act.

FDA regulations require that advertisements not be false, misleading, or lacking fair balance (21 CFR 202.1 et seq.). The regulations also state that an advertisement may be false, lacking in fair balance, or otherwise misleading if it "fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis" (21 CFR 202.1(e)(7)(viii)). Thus, current regulations require manufacturers to present risk information in advertisements with a prominence and readability reasonably comparable to the claims of effectiveness.

FDA has provided guidance regarding the presentation (including the format) of risk information in its May 2009 draft guidance for industry *Presenting Risk Information in Prescription Drug and Medical Device Promotion.*[6] Specifically, the draft guidance states that font size and type style can affect the prominence and readability of information in promotional materials. The draft guidance recommends that manufacturers take these factors into consideration when assessing whether promotional material is false or misleading. In addition, as noted above, the January 2004 draft guidance *Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* specifically recommends against using small print size in the brief summary. These draft guidances, when finalized, will represent FDA's current thinking on the topics they cover.

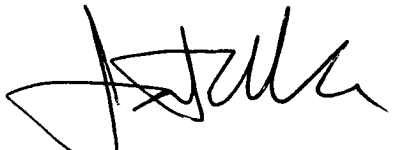
Finally, manufacturers are able to submit draft advertisements, including the brief summary, to the Agency for comment and advice (21 CFR 202.1(j)(4)).

As you acknowledge in your petition (Petition at 1, 2), several factors can affect readability, and no single factor can be determinative. As stated above, we believe that the FD&C Act, the implementing regulations, published guidance, and the availability of comment and advice from FDA provide sufficient and appropriate direction and flexibility for manufacturers to prepare DTC prescription drug brief summary materials that are readable and legible. Prescription drug advertisements that do not provide readable or legible risk information may, under our authority under the FD&C Act and implementing regulations, be subject to enforcement letters that request that manufacturers cease dissemination of such advertisements and, depending on the nature and severity of the violations, provide corrective messages.

[6] The draft guidance is available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064956.htm.

For the reasons described above, the Petition is denied. Thank you for your interest regarding this issue.

Sincerely,



Janet Woodcock, M.D.
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