AstraZeneca

July 23, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01D-0162
Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

Dear Sir or Madame:

AstraZeneca is a leading pharmaceutical company dedicated to the research and development of products and services intended to improve the health and well being of patients worldwide. As a major marketer of prescription drugs for various diseases and conditions, we have become a major sponsor of patient-oriented educational initiatives including direct-to-consumer (DTC) advertising. In principle, AstraZeneca supports the proposed draft guidance. We believe that, within all applicable laws and regulations, pharmaceutical manufacturers should be encouraged to provide useful information to patients and health care providers that will ensure the safe and effective use of prescription drugs.

As a sponsor of Direct to Consumer Advertising, AstraZeneca recognizes the importance of the proposed guidance and would like to express a number of comments. We appreciate the efforts of the Agency and acknowledge the challenges involved with gaining consensus on these issues.

Absence of Guidance for Content and Format of Patient Labeling

The Agency should take a more direct approach in expressing its expectations with regard to the content and format of approved patient labeling, including standards for reading comprehension. The guidance document acknowledges variability in approved patient labeling and distinguishes between those that would be an appropriate substitute for the brief summary from those that would not. No official standards exist for patient labeling for drugs that do not require Medication Guides. According to CFR 21 §208.1(a) Medication Guides are required by FDA when the agency determines that a prescription drug poses a serious and significant public health concern requiring distribution of FDA-approved patient information. We assume that the intent of this proposed guidance is not to dictate content and format of approved patient labeling. Rather, its intent is to provide guidance for DTC sponsors with *existing* approved patient labeling. We believe that regardless of the intent of the guidance, that it will become a patient labeling standard by default. We believe that consideration should be given to a more comprehensive labeling guidance that addresses the subject more directly in addition to the proposed advertising guidance. In the absence of a more comprehensive guidance on patient labeling, we believe the current approach may perpetuate variability in approved patient labels that may not ultimately be desirable.

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If and when the Agency issues additional guidance on this matter, it should also consider stating a goal for review and approval times for labeling amendments that include patient package inserts. This would provide additional incentive for manufacturers to provide more useful information to patients in the form of approved patient labeling and encourage its use in consumer-directed advertisements.

Separate Standards for the Brief Summary in DTC Advertisements

As stated in CFR 202.1(e)(3)(iii) and acknowledged in the proposed guidance, the information relating to side effects and contraindications shall disclose each specific side effect and contraindication contained in required, approved or permitted labeling for the advertised drug dosage forms. However, the proposed guidance allows for the abbreviation of this requirement as long as the patient labeling used in the advertisement has been approved by the Agency. It is not clear why complete disclosure of important risk information would be required for a professional brief summary when incomplete disclosure of risk information is acceptable as long as it is in patient-friendly language and has been approved by the Agency. It seems somewhat illogical that there exist two separate standards for meeting the disclosure requirements of the brief summary. Ultimately, there should be one standard that applies for all brief summaries.

Once again, AstraZeneca acknowledges the efforts of the Agency and we appreciate the opportunity to comment on this issue. We hope that we can continue to have the opportunity to help foster a more patient-friendly approach to labeling and other forms of drug information and education.

Sincerely,

Preeti Pinto
Senior Director
Promotional Regulatory Affairs

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