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July 23, 2001

MERCK

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

Re: Docket Number 01D-0162
Draft Guidance for Industry: Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements

To Whom It May Concern:

Background
Merck & Co., Inc., is a leading research-driven pharmaceutical products and services company. Merck discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health, directly and through its joint ventures. Merck fully supports the concept of direct-to-consumer (DTC) advertising for prescription medicines. Through DTC advertising, sponsors provide the general public with access to important disease information that can help patients identify and report important conditions to their physicians and health care providers. Consumer ads serve as an important link to information about available treatments and may encourage undiagnosed or at-risk patients to seek advice from a healthcare professional.

We have worked closely with the FDA Division of Drug Marketing, Advertising and Communications to implement a number of help-seeking and product-specific DTC programs for medical conditions and diseases such as high cholesterol, osteoarthritis, osteoporosis, asthma and male pattern baldness. We believe that this relationship has resulted in DTC programs that provide clear, balanced product and disease information for consumers and has enhanced the quality of interactions between consumers and their physicians.

FDA invited comments on the Agency's draft guidance, "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." In the draft guidance, DDMAC indicates that FDA does not intend to object to the use of FDA-approved patient labeling to fulfill the requirement that DTC print advertisements contain a brief summary of the product's risks.

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Merck remarks

Merck agrees with FDA's assessment that patient-directed labeling contains information that patients are likely to find helpful in deciding whether to discuss with their health care provider the possible usefulness of the product for themselves, and that patient labeling that comprehensively addresses the product's most common and serious risks is a suitable means of communicating risk information to patients.

Merck supports the draft guidance in principle.

However, Merck notes that the guidance states:

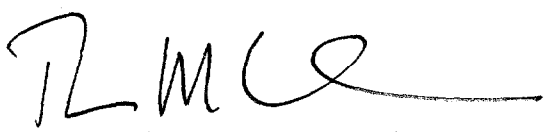
> "The Agency believes that approved patient labeling that comprehensively addresses the product's most serious and most common risks is a suitable means of communicating risk information to patients. Therefore, FDA does not intend to object to the use of this labeling, reprinted exactly as approved, to fulfill the requirement that DTC print advertisements contain a brief summary of the product's risks."

Merck believes that the guidance as written does not allow for the possibility of a sponsor making modifications to the non-risk information in FDA approved patient labeling. Merck believes that, in keeping with the intent of the draft guidance, FDA should explicitly state that it will not object to the use of a brief summary directed to consumers if it comprehensively addresses the most serious and most common risk information as it appears in the FDA approved patient labeling; even if the patient labeling is not reprinted in toto exactly as approved by FDA. For example, if individual approved PPI's for different formulations of the same product carry the same risk information, it should be allowable to combine them into a single document to be used as a brief summary in DTC advertising, by simply eliminating the redundant information.

Merck also believes that the guidance should clearly state that sponsors will have the discretion to use a brief summary of physician labeling as an alternative to patient labeling. Merck would object to any changes to the draft guidance that would negate sponsors' use of either patient labeling or a brief summary of the physician labeling.

Merck appreciates the opportunity to comment on this draft guidance.

Sincerely,



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