



May 10, 2004

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

**RE: Docket No. 04D-0042
Draft Guidances for Industry on Improving Information About Medical
Products and Health Conditions**

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate mission is to discover new medicines through breakthrough research and bring those medicines to people who need them. To this end, Merck spends nearly \$3 billion annually on research and development. Through a combination of state-of-the-art science and clinical research, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

As a leading human health product company, Merck supports the dissemination of consumer-directed educational information to encourage interactions between consumers and health care professionals (HCPs). Merck creates disease awareness communications and advertisements directed to consumers, also known as Direct-to-Consumer (DTC) promotion. We routinely provide patient education materials to HCPs for distribution to patients. In addition, we have implemented many consumer-directed print and broadcast campaigns for a variety of products and diseases, such as seasonal allergy, asthma, osteoporosis, high cholesterol, arthritis, HIV infection, and male pattern baldness. We believe this has resulted in DTC programs that provide clear, balanced product and disease information for consumers and that encourage appropriate patients and consumers to consult with their HCPs to learn more about treatment options. Hence, we welcome the opportunity to comment on the "Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions."¹ This response includes comments on two of the draft guidances: "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" and " 'Help-Seeking' and other Disease Awareness Communications by or on Behalf of Drug and Device Firms." Merck will not comment on the third draft guidance, "Consumer-Directed Broadcast Advertising of Restricted Devices."

¹ 69 FR 6308, February 10, 2004.

Introduction

DTC advertising educates consumers about potential treatments and is intended to encourage interaction between patients and HCPs. For this reason, Merck strongly endorses the FDA's core insight in the guidance, namely that to achieve this objective, DTC communications should use consumer-friendly language. A number of companies have converted physician brief summaries into consumer-friendly language. A number of companies have also received approval for patient package inserts (PPI)² in consumer-friendly language which can be used to satisfy the brief summary requirement.

Merck also agrees that help-seeking communications should present a responsible public health message that is free from references to any specific medication. Merck acknowledges FDA's concerns about disease awareness communications in combination with product claim or reminder advertising or both, and seeks FDA clarification of the definitions of perceptual similarity and physical or temporal proximity.

Draft Guidance - Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements

Consumer-Friendly Language

Merck supports FDA's recommendation to use consumer-friendly language³ in all parts of consumer-directed materials, including brief summaries accompanying DTC advertising. Merck has adopted consumer-friendly language for its DTC advertising.

Brief Summary Formats

Currently, a physician brief summary meets FDA regulatory requirements for fulfillment of the DTC brief summary. Because this format very clearly satisfies the law, FDA should eliminate language that refers to these documents as "less than optimal."⁴ The statement "FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks" is particularly disturbing when the regulations spell out that this is what manufacturers should include. If FDA is not satisfied with the regulations, Merck respectfully submits that FDA should engage in the rule-making process to modify the regulations.

² For this response, Merck uses the term "PPI" to mean those patient package inserts that are FDA-approved and which FDA has suggested are appropriate to fulfill the brief summary requirement in DTC advertising.

³ Brief Summary Draft Guidance, page 1, lines 34-35.

⁴ Brief Summary Draft Guidance, page 2, lines 65-71.

Highlights Format

For the reasons set forth by Merck in its response to the December 2000 FDA proposal to revise professional labeling, Merck has significant concerns regarding the inclusion of Highlights⁵ in Prescribing Information. These include:

- the concern in condensing and selecting partial risk information from a document that is intended to be read in its entirety;
- the potential for inconsistent content selection across reviewing divisions within the FDA;
- the redundancy of repeating information twice in the Prescribing Information;
- a potential for increased tendency by HCPs to rely on Highlights only instead of the entire Prescribing Information, which could result in an associated increase in liability risk for manufacturers.

Therefore, Merck does not support the use of Highlights to satisfy the brief summary requirement. Merck believes that use of approved PPI is preferable to the Highlights approach for several reasons. Implementation of the labeling changes that incorporate Highlights would require major revisions to every existing prescription drug label, a process that would take years to complete. The PPI approach would involve fewer products; i.e., those involved in DTC advertising. This approach would have a shorter implementation timeline and earlier benefit to consumers. Merck therefore would advocate the use of a PPI, a modified PPI, or a consumer-friendly brief summary for meeting the brief summary requirement rather than Highlights.

Obtaining Additional Information

The draft FDA guidance recommends that any DTC print ad remind consumers⁶ “that the information presented is not comprehensive” and include a toll-free telephone number or website address (URL) for consumers to obtain complete information. Merck currently includes URLs and toll-free telephone numbers in DTC print advertising and supports the continued inclusion of such means for provision of full product information.

⁵ Brief Summary Draft Guidance, pages 2 and 3, lines 75–88. Note: With regard to Highlights, Merck recommends that FDA consider adopting different terminology for the proposed consumer-friendly version of Highlights. Highlights, as described in the draft guidance, would be part of the professional label and written in professional language. It is confusing to use the same term to describe two documents that have different content and serve different purposes.

⁶ Brief Summary Draft Guidance, page 3, lines 118–121.

Although Merck agrees that DTC advertising should direct consumers to seek more information, Merck is concerned that the appearance of the phrase “information presented is not comprehensive” in the guidance document may be interpreted as a mandated phrase for all DTC advertising. There are many ways to inform consumers that additional information is available and that they should seek the counsel of their HCP, who ultimately makes the prescribing decision. FDA should revise this sentence to remove the implication that this specific phraseology is required and should allow manufacturers the flexibility to choose how to communicate that this information is available elsewhere.

Satisfying the Brief Summary Requirement

The guidance indicates⁷ that “FDA believes that FDA-approved patient labeling is a better vehicle for communicating risk information to consumers than lengthy, technical FDA-approved professional labeling.” Although Merck believes that a PPI is an appropriate format for conveying this information, Merck does so with the caveat that in some instances, a PPI is not available. In cases where Merck has an approved PPI, it is used to satisfy the brief summary requirement. In those cases where a PPI is not available, Merck has converted the physician brief summary into consumer-friendly language. Merck believes that either format satisfies the brief summary requirement.

Merck believes that FDA should revise its draft guidance to acknowledge that these types of documents do satisfy the regulatory requirements relating to the brief summary provision and to remove any implication that such documents do not satisfy the brief summary requirement.⁸

Merck supports the FDA’s recommendation for more widespread use of PPI for fulfillment of the brief summary requirement in the draft guidance. Developing PPI for use as patient labeling would serve two purposes: (1) it would provide patient labeling in consumer-friendly language for use in trade packaging and (2) it could be used, as described in the draft guidance, to fulfill the brief summary requirement.

Using a Modified PPI

Merck agrees that, for use as a brief summary, the PPI could, in some cases, be revised to eliminate or condense information, such as dosing and administration, how supplied, disease information, or a combination of these types of information.⁹

⁷ Brief Summary Draft Guidance, page 4, lines 139-141.

⁸ Brief Summary Draft Guidance, page 3, lines 112-114.

⁹ Brief Summary Draft Guidance, page 4, lines 152-156.

Presentation of Risk Information in the Main Body of an Advertisement

Under FDA regulations, the benefits presented in any branded advertising or promotion for prescription medications are to be balanced with risk information. In print advertising, risk information should be relevant to the benefit copy included in the main body of the ad.¹⁰ This holds true for professional print advertising as well as DTC print advertising. The draft guidance document states that presentation of risk information in the main body of the ad may be acceptable to FDA in a number of formats including, but not limited to, in text and in a “risk information window.”¹¹ Merck believes that there are many effective ways to present risk information that is required to balance benefits presented in the main body of the ad. Merck recommends that FDA continue to allow pharmaceutical manufacturers to determine, on an ad-by-ad basis, within FDA regulations, the presentational style of risk and benefit statements appearing in the body of the ad.

“Help-Seeking” and Other Disease Awareness Communications by or on Behalf of Drug or Device Firms

General Characteristics

Merck agrees that a primary characteristic of disease awareness communications is discussion of a disease or health condition without the mention of any specific drug or representation or suggestion concerning a particular drug.¹² Merck shares FDA’s belief that disease awareness communications can enhance the patient-physician relationship. For consumers and HCPs alike, these communications provide valuable information about diseases, conditions, and symptoms and help support appropriate diagnosis and treatment by HCPs through increased awareness of etiology and symptoms.¹³ Also, help-seeking communications may reduce stigma surrounding certain conditions and thus make consumers more likely to discuss these conditions with their HCP.

Content of Disease Awareness Communications

Merck has little disagreement with the list of items included under “FDA Recommendations for the Content of Disease Awareness Communications.”¹⁴ However, Merck believes that inclusion of such a list in a guidance document is

¹⁰ In this response, the term “main body” of the ad is meant to indicate the thematic portion of the advertisement and does not include the brief summary that may appear on the adjacent page.

¹¹ Brief Summary Draft Guidance, page 7, lines 281-295.

¹² “Help-Seeking” Draft Guidance, page 1, lines 21-24. For the purpose of this response, Merck is addressing disease awareness communications for drugs and biologics only.

¹³ “Help-Seeking” Draft Guidance, page 1, lines 25-30.

¹⁴ “Help-Seeking” Draft Guidance, pages 4 and 5, lines 153-174.

inappropriate, given that disease awareness communications do not come under FDA's regulatory authority. Merck is concerned that inclusion of content guidelines in this document could be misinterpreted as an expansion of FDA's regulatory jurisdiction. Merck therefore recommends that these content guidelines for disease awareness communications be deleted from the guidance document.

Perceptual Similarity and Physical and Temporal Proximity

Merck understands the term "perceptual similarity"¹⁵ to refer to similarities between any creative elements in advertising executions: visual, graphic and/or audio components, any characters or protagonists, themes, symbols, colors, etc. that links two separate communications in the mind of a consumer. Merck is concerned that, as defined, this standard can be interpreted quite broadly and may prove difficult to implement as a useful guidance tool.

Media Placement and Proximity

The scheduling and airing or printing of DTC advertising is a complex matter that involves many parties (e.g., manufacturer, ad agency, media buying agency, television network, local network affiliate). Much of this advertising delivery network is not in the direct control of the manufacturer who produces the advertising and pays for the air time or printed page. Even with the use of well-established procedures to direct media placement, manufacturers do not always have as complete and precise control over media placement as might be understood from the discussion of temporal proximity included in the draft guidance.¹⁶ If FDA intends to evaluate, on the basis of proximity, the appropriateness of help-seeking communications in combination with reminder or product claim advertising that share common creative elements, FDA should clearly state the criteria to evaluate proximity in the final guidance.

Product Claim and Reminder Advertising

The combination of product claim and reminder advertising is not directly addressed in the draft guidance. However, because this combination has been a topic in various public forums where FDA has discussed the draft guidances, Merck seeks FDA's clarification on the matter. Merck believes that the combination of product claim and reminder advertising should have no restrictions with respect to perceptual similarity or physical or temporal proximity.

The criteria for reminder and product claim advertising are clear in the prescription drug advertising regulations. These two forms of advertising are perceptually

¹⁵ "Help-Seeking" Draft Guidance, page 6, lines 216–219.

¹⁶ "Help-Seeking" Draft Guidance, pages 6 and 7, lines 226-237.

similar by definition, in that both include product trade names, typically in the form of product logos. Because a reminder ad makes no disease or product claims and a product claim ad includes appropriate balance information, Merck believes that the combination of reminder and product claim ads is appropriate and acceptable under existing regulations, regardless of perceptual similarity or proximity.

Only Drug in Class and Single-Product Companies

The draft guidance states¹⁷ that if “FDA determines that a supposed disease awareness communication impliedly identifies a particular drug or device, which may be the case when a communication relates to a drug or device that is the only drug or device in its diagnostic or therapeutic class or the only product manufactured by a company,^[1] then the agency may treat the communication as labeling or advertising under the act.”

Merck believes that the draft guidance is too restrictive with respect to single drugs in a therapeutic class or a manufacturer with only one product. Disease awareness communications should be treated no differently in these situations than they would be for the case of a manufacturer with multiple products in a therapeutic category.

In the past, Merck has been the sole manufacturer of various drugs for a number of underdiagnosed and undertreated life-threatening and quality-of-life diseases, such as benign prostatic hyperplasia and osteoporosis. In these cases, Merck developed appropriate disease-only awareness programs for consumers and HCPs that Merck believes were helpful to consumers and enabled physician-patient discussion.

In an age of biotechnology and faster identification and processing of new molecular entities, FDA must consider that there is likely to be a wide range of novel treatments for either underdiagnosed or undertreated conditions or widespread conditions in which there is patient/physician dissatisfaction with available treatments. To limit any manufacturer who has made a large investment in researching these life-enhancing or life-saving treatments from informing and educating the medical community and the general public about the diseases or conditions that may benefit from treatment is counterproductive.

As written, the draft guidance may seriously diminish manufacturers’ willingness to create disease-only awareness communications in these situations. If FDA seeks to encourage disease awareness communications, it should be particularly interested in encouraging such communications in the instance where a novel treatment has been discovered.

¹⁷ “Help-Seeking” Draft Guidance, page 4, lines 121-125.

In closing, Merck appreciates the opportunity to comment on the draft guidances. Merck shares FDA's objectives regarding consumer-friendly brief summary and appropriate use of help-seeking and disease awareness communications in combination with reminder or product claim advertising.

Sincerely,

A handwritten signature in cursive script that reads "Diana M. Scott". The signature is written in black ink and is positioned above the typed name.

Diana M. Scott
Vice President
Marketing Services