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May 6, 2004

Via fax and UPS

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

Re: Docket No. 2004D-0042

Draft Guidance for Industry on Improving Information About Medical Products and Health Conditions [Federal Register/ Volume 69, No. 27, page 6308]

Dear Sir/Madam:

Aventis Pharmaceuticals appreciates the opportunity to comment on the above-referenced docket with regards to the draft guidance entitled "*Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements.*"

The guidance provides recommendations on the disclosure of risk information in prescription drug product advertisements directed toward consumers in print media. It describes how sponsors can use FDA-approved patient labeling or Highlights of the FDA-approved professional labeling to provide risk information in consumer-directed print advertisements for prescription drugs. The guidance also encourages the use of consumer-friendly language in advertisements that use highlights of FDA-approved professional labeling to present risk information.

We offer the following comments and questions for your consideration.

GENERAL COMMENTS:

Aventis recommends that the Agency clarify in future guidance the process for reviewing the proposed labeling text that accompanies the advertisement by either the FDA reviewing division or Division of Drug Marketing, Advertising and Communications. Additionally, consideration should be provided to the type of Agency approval that is required for revised consumer-directed labeling, especially when the complete text of approved patient labeling is not used or the prescribing information Highlights section is rewritten in consumer-friendly language.

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SPECIFIC COMMENTS:

III. Options for Disclosing Risk Information in Consumer Directed Print Advertisements B. Highlights 1. Before the Proposed Rule Becomes Effective

Recommendation: If the risk information is provided based on the Highlights section of the Proposed Physician Labeling Rule¹ prior to it becoming effective, Aventis requests clarification on whether the proposed Highlights text would need to be submitted in advance to the Agency for prior approval to use this risk information in consumer-directed print advertising.

III. Options for Disclosing Risk Information in Consumer Directed Print Advertisements B. Highlights 3. FDA Recommendations On Use of Consumer-Friendly Language

Recommendation: Aventis offers the following suggestions:

1. The use of a “consumer version” of the Highlights section of labeling under the Proposed Physician Labeling Rule should depend on the content of the final rule, once published.
2. Under the Proposed Physician Labeling Rule, the Highlights section must be “*limited in length to an amount that, if printed in 2 columns on one side of a standard size piece of typing paper (8 1/2 by 11 inches), single spaced, in 8-point type with 1/2-inch margins on all sides and between columns, would fit on one-half of the page.*”

In order to comply with this space and format requirement, products with extensive safety information may be required to only mention the terms in the prescribing information Highlights section with a cross-reference to the comprehensive labeling sections. In these cases, using the Highlights section for consumer advertising would require rewriting the Highlights section, not only to convert the text to consumer-friendly text, but also to include all information necessary to assure safe use of the product. This would also require additional review and approval of the proposed text by the FDA, adding an additional burden on both the FDA and the sponsor.

If this is the decided option, Aventis recommends that future guidance clarify ways in which to deal with the Highlights section for products that may be considered incomplete without the accompanying prescribing information.

¹ Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Labels (65 FR 81082, December 22, 2000)

On behalf of Aventis Pharmaceuticals, we appreciate the opportunity to comment on the *Draft Guidance for Industry on Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements* and are much obliged for your consideration.

Sincerely,

A handwritten signature in black ink that reads "Steve A. Caffé for S.C.". The signature is written in a cursive style with a large initial "S" and "C".

Steve Caffé, M.D.

Vice President, Head US Regulatory Affairs