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July 19, 2001

Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 01D-0162 - Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements (*66 Federal Register 20468; April 23, 2001*)

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified global health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic, infectious diseases, neurological disorders and oncology. In 2000 alone, Bristol-Myers Squibb dedicated more than $1.8 billion for pharmaceutical research and development activities. The company's more than 4,300 scientists are committed to discover and develop best in class, therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises more than 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on FDA's proposed guidance on **Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements**.

Summary of BMS Comments

We support the U.S. FDA's proposal to provide guidance in this area. However, there are certain aspects of the proposed guidance that require clarification and/or modification, which we have cited below.

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BMS COMMENTS:

Our primary concerns are as follows:

X The proposed guidance should be revised to clarify that the use of FDA-approved patient labeling that comprehensively addresses the product's most serious and most common risks would be one, but not the only, way to satisfy the brief summary requirement under the regulations. Consequently, we would like the proposed guidance to state that a sponsor who addresses every risk included in an advertised drug's approved labeling would also fulfill the brief summary requirement under the regulations.

X Should 21 CFR 202.1(e)(3) (iii), be amended to specify that the use of FDA- approved patient labeling that comprehensively addresses the product's most serious and most common risks satisfies the brief summary requirement? Currently, the regulation at 21 CFR 202.1(e)(3) (iii) only requires that a sponsor "disclose each specific side effect and contraindication" (emphasis added). It would seem prudent that an addendum incorporating this "new" standard specific to consumers be introduced for regulatory action.

X The following paragraph in the proposed guidance is confusing and requires clarification:

> Because the regulations do not specify how to address each risk, sponsors can use discretion in fulfilling the brief summary requirement under 202.1 (e)(3) (iii). Frequently, sponsors print in small type, verbatim, the risk-related sections of the approved product labeling (also called the package insert, professional labeling, prescribing information, and direction circular). This labeling is written for health professionals using medical terminology. FDA believes that this is one reasonable way to fulfill the brief summary requirement for print advertisements directed toward health professionals, but may be difficult for consumers to understand. (emphasis added)

In particular, the final sentence seems to imply that the regulation at 21 CFR 202.1(e)(3) (iii) differentiates between consumer and health professional advertisements. We would disagree. As the regulation is currently constructed, we believe that a sponsor who discloses each specific side effect and contraindication in brief summary still complies with 21 CFR 202.1(e)(3) (iii), regardless of the audience to whom the advertisement is directed. If the FDA wants to create a new standard, we ask that they do so through the appropriate rulemaking procedures.

X We recommend deleting the statement "Omitting less serious infrequent risks as well as those risks not likely to be caused by the product, may actually increase the usefulness of this labeling for its audience by making the more important risks clearer". Inclusion of this statement in the proposed guidance implies that the use of other approaches to fulfill the brief summary requirement (including an approach that discloses each specific side effect and contraindication) would be inferior.

X We believe that the following terms should be more clearly defined, either quantitatively or qualitatively, to provide proper guidance for interpretation:

- most serious
- most common
- major precautions
- frequently occurring

Conclusion

In summary, BMS recommends that the FDA refocus the proposed guidance to articulate, with more clear definitions, what the FDA would not object to when a company chooses to use FDA-approved patient labeling to fulfill the brief summary requirement under 21 CFR 202.1 (e)(3)(iii). The additional requirements implied in this guidance that go beyond those currently required by regulation would be more properly introduced under rulemaking procedures.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

Laurie Smaldone

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