



Bristol-Myers Squibb Company

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April 19, 2006

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

Re: Docket No. 2005D-0011; *Draft Guidances for Industry on the Content and Format of Labeling for Human Prescription Drug and Biological Products (January 24, 2006); Guidance for Industry, Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format*

Dear Sir or Madam:

Bristol-Myers Squibb (BMS), a diversified global health care company, is pleased to have the opportunity to offer comments on the draft guidance: *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format*. Our company's mission is to extend and enhance human life by providing the highest-quality pharmaceutical and related health care products. For this reason, we are interested in commenting on this draft guidance. Our comments are set forth below.

Summary of BMS Comments:

We believe that the draft guidance: *Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format* will assist industry in providing the practitioner important safety information in prescription drug labeling that is clear, useful, informative, and to the extent possible, consistent in content and format. We have reviewed this draft *Guidance for Industry* and have found it to be a valuable resource for providing insight into the new labeling regulations. BMS therefore commends the Agency for providing this guidance along with the accompanying draft and final Guidances and the four fictitious labeling examples.

Since this "guidance is intended to assist applicants and reviewers in drafting the WARNINGS AND PRECAUTIONS, CONTRAINDICATIONS, and BOXED WARNING sections of labeling, as described in the final rule amending the requirements for the content and format of labeling..." BMS includes several requests for general clarifications regarding this guidance, the final labeling rule and accompanying guidance documents. We propose that any clarifications in response to our comments be included in the final form of this guidance to assist the industry in a timely and expeditious implementation of this major public health initiative. Additionally, BMS would welcome the opportunity to work collaboratively with FDA and any other interested parties to address these concerns.

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General Comments:

General comments to the following sections of the draft guidance document and requests for Agency clarification are listed below. Where relevant, illustrations from the fictitious labeling example documents are provided.

Contraindications Section

According to the final rule (§§ 201.57(c)(5) and 201.57(a)(9)), this guidance, and the draft Labeling Implementation guidance, if there are no known contraindications for a drug, this section must state "None" and this term must be placed in both the Full Prescribing Information (FPI) and Highlights section. By codifying this restricted term, there is concern with the potential exclusion of contraindications that may occur in the future. Therefore, we recommend that the Agency give consideration to the use of alternative statements such as "None known" in order to clarify that new contraindications may become known in the future.

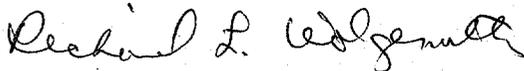
According to the format section of this guidance, FDA recommends that each contraindication be identified by its own subheading. However, BMS is unable to locate an example in any of the fictitious labeling documents where contraindications have been listed under subheadings as defined per §§201.57(c) and 201.56(d)(2). In fact, the Imdicon example uses bulleting in lieu of subheadings. We recommend that FDA provide clarification as to which approach is supported by the Agency.

Glossary

We would like to note that there are several minor inconsistencies between the text presented in the Glossary sections of this draft guidance and the final Adverse Reactions guidance. Paragraphs two through four of the draft guidance Glossary are not aligned with the final Adverse Reactions guidance Glossary. We recommend alignment of the glossaries at this time.

BMS appreciates the opportunity to provide comment and respectfully recommend that FDA give consideration to our request for clarifications and recommendations. We believe that any further clarifications from the Agency which can be reflected in this finalized guidance document will enable a streamlined and expeditious implementation of the final rule, and we would be pleased to provide additional pertinent information as may be requested.

Sincerely,



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