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Laurie Smaldone, M.D.
Senior Vice President
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June 19, 2003

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

Re: Docket No. 03D-0061; Draft Guidance for Industry on Comparability Protocols - Chemistry, Manufacturing, and Controls Information, [68 Federal Register 8772-8773 (February 25, 2003)]

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide 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 and infectious diseases, neurological disorders, and oncology. In 2002 alone, Bristol-Myers Squibb dedicated $2.2 billion for pharmaceutical research and development activities. The company has more than 5,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises of approximately 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on the FDA draft guidance for industry entitled "Comparability Protocols - Chemistry, Manufacturing, and Controls Information".

Specific comments are provided in bullet format below.

- Reference is made to lines 288-301. Modifications to a comparability protocol should be reported and approved according to the appropriate reporting category for the change. For example, a change in a test method to comply with an official compendium would be filed in an Annual Report. If this change in test method also affects an approved comparability protocol and the protocol is referenced as part of the request to make the change, the modified protocol should be acceptable for use because the change is considered minor.

03D-0061 C12

- Please provide further clarification on the expectations for a "detailed description" as listed in line 327 - "a detailed description of the proposed changes clearly.....". Too much granularity in the detailed description will limit the usefulness of a given protocol since it will be difficult to anticipate the precise nature of every change that is to be made in the future as a result of development work. For example, a comparability protocol could be filed for modifications to a complex fermentation process without detailing what components or conditions would be changed.

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

Laurie F. Smaldone, M.D.
Sr. Vice President
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