

Bristol-Myers Squibb Pharmaceutical Research Institute

P.O. Box 4000 Princeton, NJ 08543-4000

609 252-5992 Fax: 609 252-3619

laurie.smaldone@bms.com

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Laurie Smaldone, M.D.

Regulatory Science & Outcomes Research

September 30, 2000

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

Re: Docket No. 00D-0186; International Conference on Harmonisation; Draft Guidance on M4 Common Technical Document; Availability [Federal Register Vol. 65, No. 165, page 51621 (August 24, 2000)]

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, beauty care, nutritionals and medical devices. We are a leading company in the development of innovative therapies for cardiovascular, metabolic, oncology, infectious diseases, and neurological disorders.

The Bristol-Myers Squibb Pharmaceutical Research Institute (PRI) is a global research and development organization that employs more than 4,300 scientists worldwide. PRI scientists are dedicated to discovering and developing best in class, innovative, therapeutic and preventive agents, with a focus on ten therapeutic areas of significant medical need. Currently, the PRI pipeline comprises more than 50 compounds under active development. In 1999, pharmaceutical research and development spending totaled \$1.4 billion.

For these reasons, we are very interested in and well qualified to comment on this FDA proposal concerning the Draft Guidance on M4 Common Technical Document.

We commend FDA for supporting this initiative. The proposed requirements for preparation of the Common Technical Document will greatly simplify and streamline the process of compiling marketing applications for the three ICH regions, and will reduce the burden on industry. We have no problems with or comments on the draft guidelines and believe they are very well written. However, we feel that additional guidance on the content of the Regional Module I for the United States is needed.

In particular, we feel that clarification of the content, format, and organization of the Regional

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Module I (Administrative Information and Prescribing Information) is needed. The ICH M4 documentation states that "this section should contain documents specific to each region; for example, application forms or the proposed label for use in the region. The content and format of this module can be specified by the relevant Regulatory Authorities (Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human use, page 2, Released for Consultation, 20 July 2000, at Step 2 of the ICH Process)." Clear guidance on the format and content of Module I will be necessary for full implementation and adoption of the Common Technical Document in the United States.

Bristol-Myers Squibb Company appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our request for guidance. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

A handwritten signature in cursive script, reading "Laurie F. Smaldone". The signature is written in black ink and is positioned above a horizontal line.

Laurie F. Smaldone, M.D.
Senior Vice President
Worldwide Regulatory Sciences
And Outcomes Research

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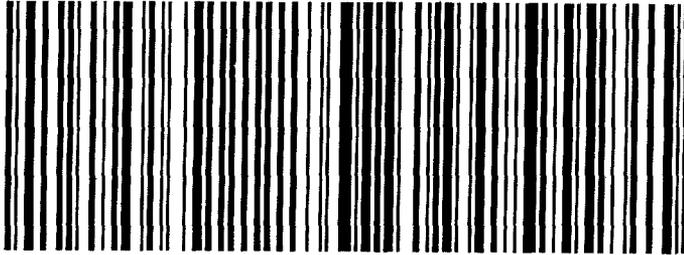
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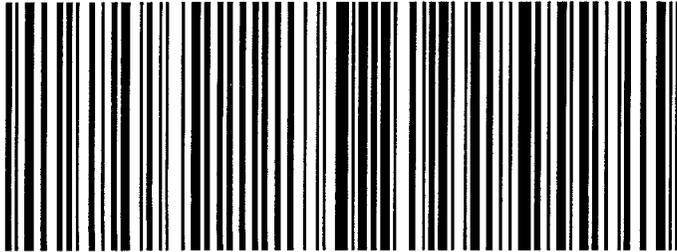
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