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August 5, 2003
Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003D-0231; BMS ID No. 422. Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format--Postmarketing Periodic Adverse Drug Experience Reports; *(June 24, 2003)*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 approximately 50 compounds under active development.

For these reasons, we are well qualified to review the Draft Guidance developed by FDA on Providing Regulatory Submissions in Electronic Format for Postmarketing Periodic Adverse Drug Experience Reports.

We commend the FDA on the development of this Draft Guidance that was based on experiences gained during piloting the procedures described in the document with BMS and furthers the harmonization efforts of ICH as they relate to the electronic exchanges of safety data utilizing the E2BM and M2 EWG step 4 documents.

BMS does not have any comments on this Draft Guidance as it proposes the implementation of the relevant ICH step 4 documents without modifications or contradictions. We would be pleased to provide additional pertinent information as may be requested.

2003D-0231 C2

Sincerely,

Laurie F. Smaldone, M.D.
Senior Vice President
Global Regulatory Sciences
Bristol-Myers Squibb