



Bristol-Myers Squibb Company

Worldwide Consumer Medicines

1350 Liberty Avenue Hillside, New Jersey 07205 908 851-2400

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May 31, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Attention: Charles Ganley, MD, Director
Division of OTC Drug Products (HFD-560)
Food and Drug Administration

Re: Docket No. 77N-0094, CP 15
Internal Analgesic, Antipyretic, and Antirheumatic
Drug Products for Over-the-Counter Use

Request for Teleconference to Discuss February 5, 2002 FDA Letter

Dear Dr. Ganley:

Reference is made to Bristol-Myers Squibb's August 1, 2001 meeting request and draft clinical study proposal for a trial comparing the effects of the combinations of aspirin (ASA) 500mg/acetaminophen (APAP) 500mg/caffeine 130mg (EES 130) and ASA 500mg/APAP 500mg/ caffeine 65mg (EES 65) with APAP 1000mg alone.

Reference is also made to the Agency's February 5, 2002 reply, wherein the Agency commented on the proposal and offered us the opportunity for a teleconference to clarify any questions generated by the Agency's comments. Bristol-Myers Squibb (BMS) is formally requesting the scheduling of a teleconference with the Division to discuss several questions raised by the Agency's comments.

We believe that many of the issues raised in the February 5, 2002 letter will be answered by providing the Agency with a full protocol, rather than the protocol outline we submitted in August 2001. Subsequent to the teleconference, we will submit the full protocol, which will reflect the outcome of our discussion.

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We would like to schedule the teleconference in the near future. The following is a list of anticipated individuals representing BMS Worldwide Consumer Medicines:

- Jorge Insuasty, MD – Vice President, Research & Development
- Howard Hoffman, MD – Executive Medical Director, Clinical Research
- Sandra Hamelsky, MPH, Ph.D. – Director, Clinical Research
- Rich Cuprys – Senior Director, Regulatory Affairs
- Jean Battikha – Associate Director, Statistics and Data Management
- Donna Coughlin – Associate Director, Regulatory Affairs

We request that the following Agency personnel attend the meeting:

- Charles Ganley, MD – Director (HFD-560)
- Linda Katz, MD – Deputy Director (HFD-560)
- Walter Ellenberg, Ph.D – Project Manager (HFD-560)

We would be available to meet at a mutually convenient date and time.

If you have any questions or comments regarding this submission please contact me at (908) 851-6126.

Sincerely,



Rich Cuprys
Senior Director
Regulatory Affairs
Bristol-Myers Squibb Company
Worldwide Consumer Medicines
1350 Liberty Avenue
Hillside, NJ 07205

CC: Walt Ellenberg, Ph.D. (HFD-560)

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