



FILE COPY

December 27, 2001

C. Boyden Gray
Wilmer, Cutler & Pickering
2445 M Street, NW
Washington, DC 20037

On behalf of Bristol-Myers Squibb Company

Dear Mr. Gray:

Your petition requesting the Food and Drug Administration to issue new or amend existing regulations which permits the FDA to approve certain generic drug applications that omit pediatric labeling information, while authorizing the FDA to continue taking action to protect children's health and safety was received by this office on 12/26/01. It was assigned docket number 01P-0586/CP 1 and it was filed on 12/27/01. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink, which appears to read "Lyle D. Jaffe".

Lyle D. Jaffe

Dockets Management Branch

01P-0586

ACK1