



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 14, 2001

Mr. Andrew N Gustafson, Ph.D.
Vice President, US Regulatory Affairs
GlaxoSmithKline
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Gustafson:

Your petition requesting the Food and Drug Administration to reformat label for prescription drug for asthma medication was received by this office on 06/13/01. It was assigned docket number 01P-0268/CP 1 and it was filed on 06/12/01. 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,

Gloria Ortega
Dockets Management Branch

01P-0268

ACK 1