



Food and Drug Administration
Rockville, MD 20857

November 5, 2004

John M. Baldoni, Ph.D.
David M. Cocchetto, Ph.D.
GlaxoSmithKline
U.S. Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101-7929

Dear Dr. Baldoni and Dr. Cocchetto:

Your petition requesting the Food and Drug Administration to refrain from receiving, reviewing, and approving any ANDA for a nasal mupirocin calcium product that contains the amorphous form of the active pharmaceutical ingredient, was received by this office on 11/5/2004. It was assigned docket number 2004P-0488/CP 1 and it was filed on 11/5/2004. 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,

/s/

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

