



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

December 15, 2004

Wayne H. Matelski
Arent Fox
1050 Connecticut Avenue, NW
Washington, DC 20036

Dear Mr. Mateski:

Your petition requesting the Food and Drug Administration to Determine that AstraZeneca LP's Xylocaine (lidocaine) 10% Oral Spray (NDA 14-394) was voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy, was received by this office on 12/15/2004. It was assigned docket number 2004P-0550/CP1 and it was filed on 12/15/2004. 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/

Jennie C. Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management