



JUN 14 2005

Food and Drug Administration
Rockville MD 20857

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Mr. Wayne H. Matelski
Arent Fox PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

Re: Docket No. 2004P-0550/CP1

Dear Mr. Matelski:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on December 15, 2004. Your petition requests that the Agency determine whether AstraZeneca LP's Xylocaine (lidocaine) 10% Oral Spray was voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy.

FDA has yet to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0550

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