



JUN 29 2005

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Kalpana Rao
Vice President, Regulatory Affairs (Global)
Taro Pharmaceuticals USA, Inc.
5 Skyline Drive
Hawthorne, NY 10532

Subject: Citizen Petition Dated June 22, 2005, Regarding Lidocaine Hydrochloride Injection, USP, 2%

Dear Ms. Rao:

This letter is to confirm our telephone conversations of Friday, June 24, and Wednesday, June 29, regarding a citizen petition you filed with FDA's Division of Dockets Management. In that petition you asked that FDA take certain actions with respect to Astra-Zeneca's discontinued product, Xylocaine (NDA 6-488). The actions were requested in the belief they were necessary in order for your company to submit an abbreviated new drug application for lidocaine hydrochloride injection, USP, 2%.

As we discussed, FDA has already initiated administrative actions that make the actions requested in the petition unnecessary. Namely, FDA will designate in the Orange Book a currently marketed lidocaine hydrochloride injection, USP, 2%, product (NDA 16-801) as the reference listed drug.

As we agreed, a copy of this letter will be filed with FDA's Dockets Management Division with the instruction that this letter constitutes your formal withdrawal of the citizen petition. Thanks for your quick attention to this matter.

Sincerely yours,

David T. Read
Regulatory Counsel
Office of Generic Drugs (HFD-7)
Center for Drug Evaluation and Research

cc: HFA-305 (Division of Dockets Management)
ATTN: Lyle Jaffe

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