U.S. FOOD & DRUG ADMINISTRATION

FEB 12 2020

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-5929

Re: Docket No. FDA-2019-P-3903

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 16, 2019. Your petition requests that the Agency designate lidocaine hydrochloride oral solution USP, 2%, approved under abbreviated new drug application (ANDA) 040014 held by Hi-Tech Pharmaceuticals as a reference standard.

FDA has been unable to reach a decision on your petition due to 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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