March 19, 2020

David L. Rosen, BS Pharm., JD
Foley & Lardner LLP
Washington Harbour
3000 K Street, N.W.
Washington, D.C. 20007-5143

Re: Docket No. FDA-2019-P-4515

Dear Mr. Rosen:

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 September 26, 2019. Your petition requests that the Agency designate Propranolol Hydrochloride Tablets USP 80 milligrams, approved under abbreviated new drug application 070178 held by Watson Laboratories Inc., as the new reference standard in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

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