Amy Schutte
Senior Associate
Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

Re: Docket No. FDA-2019-P-4879

Dear Ms. Schutte:

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 October 18, 2019. Your petition requests that the Agency designate Nitrofurantoin Oral Suspension, 25 mg/5 mL, approved under abbreviated new drug application (ANDA) 201355 held by Nostrum Laboratories Inc., as a 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 Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.05.29 13:39:18 -04'00'

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