Seth Shapiro
Director, Regulatory Affairs, CMC Pharma
Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Re: Docket No. FDA-2019-P-2853

DEC 06 2019

Dear Mr. Shapiro:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on June 11, 2019, and submitted on behalf of Fresenius Medical Care North America (FMCNA). Your petition requests that the Agency designate each of FMCNA's Delflex Peritoneal Dialysis Solution with 1.5%, 2.5%, and 4.25% Dextrose products approved under New Drug Application (NDA) 018883 and NDA 020171 as both a reference listed drug and a reference standard in FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book)[1].

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

[1] The Orange Book is available at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm