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

September 18, 2020

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

Dear Mr. Shapiro:

This letter responds to your citizen petition received on June 11, 2019 (Petition), requesting that the Food and Drug Administration (FDA or Agency) designate each of Fresenius Medical Care North America's (FMCNA) 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 (RLD) and a reference standard (RS) in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[1]

Since the time the Petition was submitted, FDA has updated the Orange Book to designate each of FMCNA's Delflex Peritoneal Dialysis Solution with 1.5%, 2.5%, and 4.25% Dextrose products, approved under NDA 018883 and NDA 020171, as an RLD and as an RS. Therefore, we dismiss the Petition as moot.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
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Date: 2020.09.15 16:16:10 -04'00'

Patrizia Cavazzoni, M.D.
Acting Director
Center for Drug Evaluation and Research

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