



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 12, 2019

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

Sent via email to: seth.shapiro@fmc-na.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA designate NDA 018883 and NDA 020171 in the Orange book as RLD Reference Listed Drug and RS Reference Standard was received by this office on 06/11/2019.

It was assigned docket number FDA-2019-P-2853. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of Operations (OO)