

LAW OFFICES  
**HYMAN, PHELPS & MCNAMARA, P.C.**

KURT R. KARST

700 THIRTEENTH STREET, N.W.  
SUITE 1200  
WASHINGTON, D.C. 20005-5929  
(202) 737-5600

FACSIMILE  
(202) 737-9329

www.hpm.com

Direct Dial (202) 737-7544  
kkarst@hpm.com

August 2, 2021

**BY ELECTRONIC SUBMISSION**

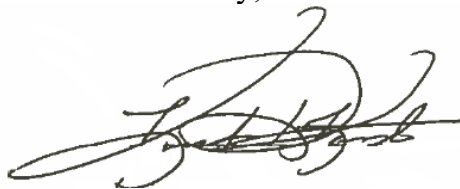
Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

**RE: Docket No. FDA 2020-P-1403**

Dear Sir or Madam:

Pursuant to FDA request, and in accordance with FDA's October 2020 final guidance, "Referencing Approved Drug Products in ANDA Submissions," Petitioner requests withdrawal of the above-referenced citizen petition asking that FDA designate Doxycycline Hyclate for Injection, 100 mg Base/Vial and 200 mg Base/Vial, both approved under Abbreviated New Drug Application 062475, held by Fresenius Kabi USA LLC, as a new Reference Listed Drug ("RLD"). FDA, in its October 2020 guidance, states that applicants now may submit controlled correspondence to ask FDA to designate a new or additional RLD. Because the controlled correspondence pathway now is available, a formal response to Docket No. 2020-P-1403 is no longer necessary.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kurt R. Karst', with a stylized flourish at the end.

Kurt R. Karst