Sharif Ahmed
Principal Consultant
Lachman Consultants Services Inc.
1600 Stewart Ave.
Westbury, NY 11590

Susan Todd
Teligent Pharma, Inc.
105 Lincoln Ave.
Buena, NJ 08310

Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Washington, DC 20005-9329

September 17, 2020

Re: Docket Nos. FDA-2017-P-6291, FDA-2017-P-6479, and FDA-2020-P-0284

Dear Petitioners:

This letter is a consolidated response to three citizen petitions having docket numbers referenced above. On October 26, 2017, the Food and Drug Administration (FDA or Agency) received a petition from Lachman Consultant Services Inc., FDA-2017-P-6291, requesting that FDA designate nicardipine hydrochloride injection, 25 mg/10 mL, approved under new drug application (NDA) 022276 held by Excela Pharma Science, as an additional reference listed drug (RLD) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).[1] On November 13, 2017, FDA received a petition from Teligent Pharma, Inc., FDA-2017-P-6479, requesting that FDA designate an additional RLD for nicardipine hydrochloride injection, 25 mg/10 mL. On January 16, 2020, FDA received a petition from Hyman, Phelps & McNamara, P.C. , requesting that FDA designate nicardipine hydrochloride injection, 25 mg/10 mL, approved under NDA 022276, as both an RLD and a Reference Standard.

Since the time these petitions were submitted, FDA has updated the Orange Book to designate nicardipine hydrochloride injection, 25 mg/10 mL, approved under NDA

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

022276, as both an RLD and a Reference Standard. Therefore, we dismiss the petitions as moot.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300121270, cn=Douglas C. Throckmorton -S
Date: 2020.09.17 15:36:08 -04'00'

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