Kristi Norris, PhD
Vice President, Regulatory Strategy
Camargo Pharmaceutical Services, LLC
800 Taylor Street, Mill No. 1, Suite 101
Durham, NC 27701

May, 19, 2021

Re: Docket Nos. FDA-2020-P-2244 and FDA-2020-P-2245

Dear Ms. Norris:

This letter responds to your citizen petitions received on December 1, 2020, requesting that the Food and Drug Administration (FDA) determine whether Isoptin (verapamil hydrochloride) tablets, 40 milligrams (mg), 80 mg, and 120 mg, and Calan (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Isoptin (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and Calan (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Isoptin (verapamil hydrochloride) tablets, 40 mg, 80 mg, and 120 mg, and Calan (verapamil hydrochloride) tablets, 40 mg, 80 mg, 120 mg, and 160 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces FDA's determination. If you require any further information, please feel free to call me at (301) 796-3601.

Sincerely,

Nicole K. Mueller -S

Digitally signed by Nicole K. Mueller -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300170462, cn=Nicole K. Mueller -S
Date: 2021.05.19 10:02:56 -04'00'

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure