Michelle R. Ryder
Executive Director
Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

April 27, 2022

Re: Docket No. FDA-2022-P-0475

Dear Ms. Ryder:

This letter responds to your citizen petition received on March 29, 2022, requesting that the Food and Drug Administration (FDA) determine whether the reference listed drug, Cleocin Phosphate in Dextrose 5% in Plastic Container (clindamycin injection in 5% dextrose), equivalent to (EQ) 6 milligram (mg) base/milliliter (mL), EQ 12 mg base/mL and EQ 18 mg base/mL, new drug application 050639, held by Pfizer Inc., has been voluntarily withdrawn from the commercial market or withdrawn from sale for reasons of safety or efficacy.

FDA has reviewed its records and determined that Cleocin Phosphate in Dextrose 5% in Plastic Container (clindamycin injection in 5% dextrose), EQ 6 mg base/mL, EQ 12 mg base/mL, and EQ 18 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Cleocin Phosphate in Dextrose 5% in Plastic Container (clindamycin injection in 5% dextrose), EQ 6 mg base/mL, EQ 12 mg base/mL, and EQ 18 mg Base/mL, 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 the FDA determination. If you require any further information, please feel free to call me at (240) 402-9674.

Sincerely,

Sungjoon Chi -S

Digitally signed by Sungjoon Chi -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sungjoon Chi -S, 0.9.2342.19200300.100.1.1=2001541263
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Sungjoon Chi
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure