Nehru Gaddipati, Ph.D., R.Ph
Nines Consult Pharma, LLC
100 Riverside Boulevard, 17E
New York, NY 10069

January 18, 2023

Re: Docket No. FDA-2022-P-1982

Dear Dr. Gaddipati:

This letter responds to your citizen petition received on August 22, 2022, requesting that the Food and Drug Administration (FDA) determine whether Ofirmev (acetaminophen) injection, 1000 milligrams (mg)/100 milliliters (mL) (10 mg/mL), approved under new drug application 022450, held by Mallinckrodt Hospital Products IP Ltd., was withdrawn from sale for safety or effectiveness reasons.

FDA has reviewed its records and determined that Ofirmev (acetaminophen) injection, 1000 mg/100 mL (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Ofirmev (acetaminophen) injection, 1000 mg/100 mL (10 mg/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 (301) 796-1546.

Sincerely,

Kaetochi C. Okemgbo -S
Digitally signed by Kaetochi C. Okemgbo -S
Date: 2023.01.18 12:38:55 -05'00'

Kaetochi Okemgbo
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure