August 23, 2022

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

Sent via email to: Nehru.gaddipati@ninespharma.com

Dear Petitioner:

Your submission requesting that the Commissioner to determine whether the Reference Listed Drug (RLD) OFIRMEV® (ACETAMINOPHEN) Injection, solution 1000 mg/100 mL (10 mg/mL) strength under New Drug Application ("NDA") 022450 held by Mallinckrodt Hosp Products IP Ltd., has been withdrawn from sale for safety or effectiveness reasons was received and processed under CFR 10.30 by this office on 08/22/2022.

It was assigned docket number FDA-2022-P-1982. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.08.23 13:22:52 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)