December 21, 2022

Martin H. Shimer, Executive Director
Lachman Consultant Services, Inc.
1600 Stewart Ave., Suite 604
Westbury, NY 11590

Sent via email to: m.shimer@lachmanconsultants.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether the previously designated Reference Listed Drug (RLD), CHIROCAINE® (Levobupivacaine Injection, 2.5 mg(base)/mL, 10 mL and 30 mL vials, 5 mg(base)/mL, 10 mL and 30 mL vials and 7.5 mg(base)/mL, 10 mL and 30 mL vials); New Drug Application (NDA) 20997, held by Purdue Pharma LP, has been voluntarily withdrawn from sale for reasons of safety or efficacy was received and processed under CFR 10.30 by this office on 12/21/2022.

It was assigned docket number FDA-2022-P-3293. 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: 2022.12.21 13:21:34 -05'00'

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