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

May 25, 2023

Re: Docket No. FDA-2022-P-3293

Dear Martin Shimer:

This letter responds to your citizen petition received on December 21, 2022, requesting that the Food and Drug Administration (FDA) determine whether the previously designated Reference Listed Drug, Chirocaine (levobupivacaine) injection, 2.5 milligrams (mg)(base)/milliliter (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mg (base)/mL, 10 mL and 30 mL vials, New Drug Application (NDA) 20997, held by Purdue Pharma LP, has been voluntarily withdrawn from sale for reasons of safety or efficacy.

FDA has reviewed its records and determined that 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10 mL and 30 mL vials, 5 mg (base)/mL, 10 mL and 30 mL vials and 7.5 mg (base)/mL, 10 mL and 30 mL vials, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain 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, 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) 796-3600.

Sincerely,

Donna C. Tran -S

Digitally signed by Donna C. Tran -S
Date: 2023.05.25 08:02:36 -04'00'

Donna Tran
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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