April 2, 2018

Firm President/CEO
Firm Name
Firm Address
City, State Zip

Dear Mr./Mrs./Dr.:

This letter is provided to confirm your awareness that all proceedings have concluded under the Drug Efficacy Study Implementation (DESI) 7337, which included Mepergan Fortis Capsule, Docket No. FDA-1981-N-0245 (formerly 81N-0080).

According to the information your firm provided to FDA's electronic Drug Registration and Listing System, your firm manufactures for commercial distribution the following prescription drug product, without an FDA-approved application:

- Meperidine Hydrochloride 50 mg and Promethazine Hydrochloride 25 mg Capsules, NDC XXXX-XXX

Your product's labeled indication is "Possibly effective: as analgesia for moderate to moderately severe pain." Your firm appears to have marketed the above-named product as a product identical, related or similar (IRS) (see 21 CFR § 310.6(b)(1)) to Mepergan Fortis (meperidine hydrochloride 50 mg and promethazine hydrochloride 25 mg) Capsule.

FDA's initial determination that Mepergan Fortis Capsule lacked substantial evidence of effectiveness for one or more labeled indications was announced in the Federal Register on April 20, 1972 (see 37 FR 7827). In that Notice, FDA provided an opportunity for a hearing regarding its initial determination. Wyeth, a Division of American Home Products, submitted a request for a hearing. Consistent with FDA's longstanding policy, as articulated in the guidance for FDA staff and industry, Marketed Unapproved Drugs – Compliance Policy Guide, the products identified in DESI 7337 as well as products IRS to those products were marketed during the pendency of the proceedings that were subsequently initiated.

On November 16, 2017, FDA's Acting Chief Scientist announced a final decision to deny the approval of the supplemental new drug application (sNDA) submitted for Mepergan Fortis Capsule. Accordingly, DESI 7337 is now closed. Companies interested in manufacturing or distributing drug products containing meperidine hydrochloride and promethazine hydrochloride

are required to obtain approval of a new drug application (NDA) or abbreviated new drug application (ANDA) prior to marketing. See Federal Register Notice, 82 FR 53507, at https://www.federalregister.gov/documents/2017/11/16/2017-24806/mepergan-fortis-capsules-final-decision-on-proposal-to-refuse-approval-of-supplemental-new-drug.

Cease Manufacture and Distribution

You should immediately cease the manufacture and distribution of the product identified above. Failure to promptly stop manufacturing and distributing this product may result in immediate enforcement action without further notice, including, without limitation, seizure and injunction. It is your responsibility to assure your firm complies with all requirements of federal law and FDA regulations.

Within 45 working days of receipt of this letter, please confirm with this office in writing that you have ceased manufacturing and distribution of the above drug product. If you no longer market the above product, your response should indicate so and the date on which you ceased production. Your listings are also required to be updated in FDA's electronic Drug Registration and Listing System for products that are discontinued, as required under section 510(j) of the Federal Food, Drug, and Cosmetic Act, to reflect the discontinuation of all drugs, including unapproved products (21 CFR 207.57(b)(1)(ii)).

Should you wish to pursue approval for your product, you should contact FDA's unapproved drugs coordinator, Dr. Sally Loewke, for assistance in communicating with the FDA on the application process for your unapproved new drugs.

Your reply to this letter should be directed to the U.S. Food and Drug Administration, Attention: Tamika White, Project Manager, Food and Drug Administration, CDER Office of Compliance, 10903 New Hampshire Avenue, Building 51, Room 5284, Silver Spring, MD 20993. If you have questions regarding any issue in the content of this letter, please contact Ms. White at 301-796-0310.

Sincerely,

F. Gail Bormel, RPh, J.D.
Director, Division of Prescription Drugs
CDER Prescription Drugs Branch
CDER Office of Unapproved Drugs and Labeling Compliance
CDER Office of Compliance