

October 12, 2017

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

Dear Mr./MS.:

We are aware that your firm distributes the following prescription drug product containing isometheptene mucate without an FDA-approved application:

- Isometheptene Mucate, Dichloralphenazone, and Acetaminophen Capsule/Tablets (isometheptene mucate, USP 65mg, dichloralphenazone, USP 100mg, and acetaminophen, USP 325mg) NDC xxxxx-xxx.
- Isometheptene Mucate, Caffeine, and Acetaminophen Capsules/Tablets (isometheptene mucate, USP 65mg, caffeine, USP 20mg, and acetaminophen, USP 325mg) NDC xxxxx-xxx.

Federal Register Notice issued January 2014

Isometheptene mucate was originally approved in 1948 for safety only; its efficacy as an adjunct to peptic ulcer treatment and for other indications, including the treatment of migraine headaches was reviewed under the Drug Efficacy Study Implementation (DESI) process [(Docket no. FDA-1975-N-0355 (formerly 75N-0185) (DESI 3265)]. In a January 10, 2014, Federal Register Notice (FRN), FDA announced that all outstanding hearing requests for DESI 3265 have been withdrawn. It is unlawful to introduce into interstate commerce any products identified in this docket, or any identical, related, or similar (IRS) product to the products in this docket, that are not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA). (See 79 FR 1875 at <http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2014-00256.pdf>.) FDA considers your product to be subject to the closed DESI 3265. Companies interested in marketing isometheptene containing drug products are required to obtain approval of a NDA or ANDA prior to marketing. However, according to the information you provided to FDA, your firm continues to distribute this unapproved drug product.

Cease Distribution

You should immediately cease the distribution of the product identified above and any additional products you distribute that were identified in Docket no. FDA-1975-N-0355 (DESI 3265) or IRS to the products in this docket. (See the docket at <https://www.regulations.gov/docket?D=FDA-1975-N-0355>.) Failure to promptly stop distributing these products 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 distribution of the above drug product and updated your listing in FDA's electronic Drug Registration and Listing System (eDRLS) as required under section 510(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) to reflect the discontinuation of all drugs, including unapproved products

[21 CFR 207.57(b)(1)(ii)]. If you no longer market the above products, your response should indicate so, including the reasons, and the date on which you ceased production. Your listings are also required to be updated for products no longer marketed. You should contact FDA's unapproved drugs coordinator, Dr. Sally Loewke, at 301-796-0710 for assistance in communicating with the FDA on the application process for your unapproved drugs.

Your reply 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