August 9, 2021

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

Dear Mr./Ms:

Your firm lists the following prescription drug product containing isoxsuprine hydrochloride in FDA's electronic Drug Registration and Listing System (eDRLS). The listing indicates this drug product does not have FDA-approved applications:

- Isoxsuprine hydrochloride tablets, USP, 10 mg (NDC xxxxx-xxx)
- Isoxsuprine hydrochloride tablets, USP, 20 mg (NDC xxxxx-xxx)

Federal Register Notice published on July 15, 2020

Vasodilan (NDA 11832), containing isoxsuprine hydrochloride, was originally approved in 1959 for safety only; its efficacy for several indications was reviewed under the Drug Efficacy Study Implementation (DESI) (Docket no. FDA-1984-N-0259 (formerly 84N-0167) (DESI 6403)). In a July 15, 2020 *Federal Register* notice, FDA announced that the Administrative Law Judge's Initial Decision—that Vasodilan had not been shown, by substantial evidence consisting of adequate and well controlled studies, to be effective for treating symptoms relating to senile dementia of the Alzheimer type (SDAT) and multiple infarct dementia and peripheral vascular disease—is the final decision of the Commissioner. 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 85 FR 42882 at https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-15248.pdf.) FDA considers your product identified above to be subject to the closed DESI 6403. Companies interested in marketing isoxsuprine hydrochloride-containing drug products are required to obtain FDA approval of an NDA or ANDA prior to marketing.

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-1984-N-0259 (DESI 6403) or IRS to the products in this docket. (See the docket at https://www.regulations.gov/document?D=FDA-1984-N-

0259-0607.) Failure to promptly stop distributing these products may result in immediate enforcement action without further notice. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

If you no longer market the above product, your response should indicate such, including the reasons why, and the date on which you ceased production. Your listings must also be updated for products no longer marketed. You should contact FDA's unapproved drugs coordinator, Dr. Sally Loewke, at 301-796-0710 for assistance with the application process for your unapproved drug.

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 eDRLS as required under section 510(j) of the Federal Food, Drug and Cosmetic Act (FD&C Act) to reflect the discontinuation of this unapproved product [21 CFR 207.57(b)(1)(ii)].

Your reply should be sent to the U.S. Food and Drug Administration, Center for Drug Evaluation and Research/Office of Compliance/Office of Unapproved Drugs and Labeling Compliance by e-mail to FDAADVISORY@fda.hhs.gov.

Sincerely,

Carolyn Becker
Director, Office of Unapproved Drugs and Labeling Compliance
CDER Office of Compliance