October 30, 2024

Firm Official Correspondent/Contact
Firm Name
Firm Address
City, State Zip
Email

Dear Mr./Ms.:

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

- Iodoquinol 1% / hydrocortisone acetate 2% / aloe polysaccharides 1% gel (NDC #####-###)
- Hydrocortisone 1% / iodoquinol 1% cream (NDC #####-###)
- Hydrocortisone acetate 1.9% / iodoquinol 1% cream (NDC #####-###)

Federal Register Notice published on July 15, 2020

Vioform (NDA 10412), containing iodochlorhydroxyquin and hydrocortisone, was originally approved in 1956 for safety only. Its efficacy for several indications was reviewed under FDA's Drug Efficacy Study Implementation (DESI) proceeding 10367 (Docket No. FDA-1980-N-0038 (formerly 80N-0012)). In a July 15, 2020 *Federal Register* notice, FDA announced that the Administrative Law Judge's Initial Decision—that Vioform had not been shown, by substantial evidence consisting of adequate and well controlled studies, to be effective for its labeled indications relating to use in various dermatoses or as anti-infective agents—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).[1]

Cease Distribution

FDA considers your product identified above to be subject to the closed DESI 10367. You should immediately cease the distribution of the product identified above and any additional products you distribute that were identified in Docket No. FDA-1980-N-0038 (DESI 10367) or IRS to the products in this docket.[2] Failure to promptly stop distributing this product 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.

[1] See 85 FR 42877 at https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-15298.pdf.
[2] See the docket at https://www.regulations.gov/docket/FDA-1980-N-0038.

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.

In addition, we encourage you to contact FDA's Office of New Drugs at ONDCommunications@fda.hhs.gov for assistance with the application process for your unapproved product.

Sincerely,

Tina Smith, M.S.
Captain, U.S. Public Health Service
Director
Office of Unapproved Drugs & Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration