



NDA 218528

TENTATIVE APPROVAL

AFT Pharmaceuticals Ltd
c/o: Chesapeake Regulatory Group, Inc
Attention: David Zuchero, MS, JD
Authorized US Agent
6574 Rive Clyde Drive
Highland, MD 20777

Dear Dr. Zuchero:

Please refer to your new drug application (NDA) dated March 26, 2023, received March 26, 2023, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Scomara (sirolimus) cream, 0.5%.

We acknowledge receipt of your amendment dated January 22, 2026, which constituted a complete response to our January 25, 2024, action letter.

(b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (Prescribing Information, Patient Package Insert, and carton and container labeling). This tentative approval determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Under section 527(a) of the FD&C Act, orphan-drug exclusivity prevents FDA from approving or licensing the same drug for the same use or indication for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of approval or licensure.

(b) (4)

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **“REQUEST FOR FINAL APPROVAL”**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved and cannot be legally marketed and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before March 22, 2026, you should amend your application accordingly.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

If you have any questions, email H. F. Van Horn III, PharmD, MBA, Senior Regulatory Project Manager, at howard.vanhorniii@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gordana Diglisic, MD
Associate Director for Therapeutic Review
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - Carton and Container Labeling

15 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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