



ANDA 218425

**ANDA APPROVAL**

Apotex Corp.  
U.S. Agent for Apotex Inc.  
Attention: Dr. Kiran Krishnan  
Senior Vice President, Global Regulatory Affairs

Dear Dr. Kiran Krishnan:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 22, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Cladribine Tablets, 10 mg.

Reference is also made to the tentative approval letter issued by this office on October 8, 2025, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Cladribine Tablets, 10 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Mavenclad Tablets, 10 mg, of EMD Serono, Inc. (EMD) NDA - 022561.

The RLD upon which you have based your ANDA, EMD's Mavenclad Tablets, 10 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,713,947 (the '947 patent)	October 16, 2026
8,377,903 (the '903 patent)	May 31, 2026
10,849,919 (the '919 patent)	November 23, 2038

Your ANDA contains paragraph IV certifications to the '947 and '903 patents under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Cladribine Tablets, 10 mg, under this ANDA. You have notified the Agency that Apotex Inc. (Apotex) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Apotex for infringement of the '947 and '903 patents in the United States District Court for the District of Delaware [Merck KGaA, Merck Serono SA, and Ares Trading SA v. Apotex Inc. and Apotex Corp., Civil Action No. 23-00655]. Although this litigation remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the FD&C Act, during which FDA was precluded from approving your ANDA, has expired.

With respect to the '919 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act that this is a method-of-use patent that does not claim any indication or other conditions of use for which you are seeking approval under your ANDA.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

### **COMPENDIAL STANDARDS**

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website at: <https://www.uspnf.com/>.

### **REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements

and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to: <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

Sincerely yours,

*{See appended electronic signature page}*

For Kendra S. Stewart, R.Ph., Pharm.D.  
CAPT, United States Public Health Service  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Catherine  
Poole

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