



ANDA 204029

**ANDA APPROVAL**

Abon Pharmaceuticals, LLC  
140 Legrand Ave  
Northvale, NJ 07647  
Attention: Jen Barrett  
Director of Quality

Dear Madam:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 23, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Clofarabine Injection, 20 mg/20 mL (1 mg/mL), Single-use Vial.

Reference is also made to the complete response letter issued by this office on May 31, 2016, and to your amendments received on June 15 and October 11, 2016; and January 30, 2017.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Clofarabine Injection, 20 mg/20 mL (1 mg/mL), Single-use Vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clolar Injection, 20 mg/20 mL (1 mg/mL) of Genzyme Corporation (Genzyme).

The RLD upon which you have based your ANDA, Genzyme's Clolar Injection, 20 mg/20 mL (1 mg/mL), is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) is 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>
5,661,136 (the '136 patent)	July 14, 2018

Your ANDA contains a paragraph IV certification to the '136 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clofarabine Injection, 20 mg/20 mL (1 mg/mL), Single-use Vial, under this ANDA. You have notified the Agency that Abon Pharmaceuticals, LLC (Abon) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that litigation was initiated within the statutory 45-day period against Abon for infringement of the '136 patent in the United States District District of New Jersey [Southern Research Institute, Et Al. v. Abon Pharmaceuticals LLC, Inc., Civil Action No. 12-cv-04709]. You have also notified the Agency that this case has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Abon was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Clofarabine Injection, 20 mg/20 mL (1 mg/mL), Single-use Vial. Therefore, with this approval, Abon is eligible for 180 days of generic drug exclusivity for Clofarabine Injection, 20 mg/20 mL (1 mg/mL), Single-use Vial. It is noted that this ANDA was not tentatively approved within the 30<sup>1</sup>-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the agency has determined that Abon has not forfeited its eligibility for 180-day generic drug exclusivity.<sup>2</sup> This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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

### **REPORTING REQUIREMENTS**

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

### **PROMOTIONAL MATERIALS**

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<sup>1</sup> For applications submitted between January 9, 2010, and July 9, 2012 containing a paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on July 9, 2012, and ending on September 30, 2015, section 1133 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144) extends this period to 40 months. For applications submitted between January 9, 2010, and July 9, 2012 containing a paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and approved or tentatively approved during the period of time beginning on October 1, 2015, and ending on September 30, 2016, section 1133 of FDASIA extends this period to 36 months. In addition, if an application was submitted between January 9, 2010, and July 9, 2012 containing a paragraph IV certification (or amended to first contain a paragraph IV certification during that period of time), and FDA has not approved or tentatively approved the application but must consider whether the applicant has forfeited exclusivity because a potentially blocked application is ready for approval, FDA will apply the 36-month period if it makes the forfeiture determination between the period of time beginning on October 1, 2015, and ending on September 30, 2016. For all other applications, the 30-month period set forth in FD&C Act section 505(j)(5)(D)(i)(IV) applies.

<sup>2</sup> ANDA 204029 was received on February 23, 2012. This ANDA was never tentatively approved and therefore was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV) of the FD&C Act. Nevertheless, the Agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed.

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

### **ANNUAL FACILITY FEES**

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1<sup>st</sup> of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR

314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. The SPL will be accessible via publicly available labeling repositories.

The Electronic Common Technical Document (eCTD) is CDER’s standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: [www.fda.gov/ectd](http://www.fda.gov/ectd).

Sincerely yours,

*{See appended electronic signature page}*

Carol A. Holquist, RPh  
Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Carol  
Holquist

Digitally signed by Carol Holquist  
Date: 5/09/2017 04:26:00PM  
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