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APPLICATION NUMBER:
ANDA 091358Orig1s000

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091358

Strides Inc.
U.S. Agent for: Onco Therapies Limited
Attention: Anil Sachdeva
Director, Regulatory Affairs
201 South Main Street, Suite #3
Lambertville, NJ 08530

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 17, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxaliplatin Injection USP, 5 mg/mL, (Preservative-Free), packaged in 50 mg/10 mL, 100 mg/20 mL, and 200 mg/40 mL Single-use Vials.

Reference is also made to the tentative approval letter issued by this office on September 28, 2011, and to your amendments dated February 21, February 24, and July 17, 2012. In addition, we acknowledge receipt of your correspondences dated February 24, July 6, and July 21, 2012, addressing patent issues associated with this ANDA.

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, your Oxaliplatin Injection USP, packaged in 50 mg/10 mL, and 100 mg/20 mL Single-use Vials is approved, effective on the date of this letter. However, because of the exclusivity issue explained below, we are unable to grant final approval to your Oxaliplatin Injection USP, 200 mg/40 mL strength. Your Oxaliplatin Injection USP, 200 mg/40 mL, remains tentatively approved.

The reference listed drug (RLD) upon which you have based your ANDA, Eloxatin Injection, 5 mg/mL, packaged in 50 mg/10 mL, 100 mg/20 mL, and 200 mg/40 mL Single-use Vials of Sanofi Aventis U.S., LLC (Sanofi), is subject to periods of patent

protection. The following patents and their expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,290,961 (the '961 patent)	July 12, 2013
5,338,874 (the '874 patent)	October 7, 2013
5,420,319 (the '319 patent)	February 9, 2017
5,716,988 (the '988 patent)	February 7, 2016

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Oxaliplatin Injection USP, 5 mg/mL, packaged in 50 mg/10 mL, 100 mg/ 20 mL, and 200 mg/40 mL Single-use Vials, under this ANDA. You have notified the agency that Onco Therapies Limited (Onco) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '874 and '988 patents was brought against Onco within the statutory 45-day period in the United States District Court for the District of New Jersey [Sanofi-Aventis U.S. LLC , Sanofi-Aventis, Debiopharm S.A. v. Strides, Inc., Onco Therapies Limited, Strides Arcolab Limited, Civil Action No. 3:12-cv-02070-JAP-LHG]. You have also notified the agency that on July 18, 2012, a settlement was reached between Onco and Sanofi and a Consent Judgment and Order resolving the litigation was entered.

I. Approval of Oxaliplatin Injection USP, 5 mg/mL, 50 mg/10 mL and 100 mg/20 mL Single-use Vials

The Division of Bioequivalence has determined your Oxaliplatin Injection USP, 5 mg/mL, packaged in 50 mg/10 mL and 100 mg/20 mL Single-use Vials, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Eloxatin Injection, 5 mg/mL, packaged in 50 mg/10 mL and 100 mg/20 mL Single-use Vials.

Under section 506A of the 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 & 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 Act.

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 may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

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.

**II. Tentative Approval of Oxaliplatin Injection USP,
200 mg/40 mL Single-use Vials.**

We are unable at this time to grant final approval of your 200 mg/40 mL strength of the drug product because another ANDA for Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials, containing a paragraph IV certification was received by this office prior to the receipt of your ANDA for this strength. This other ANDA, therefore, is eligible for 180-day generic drug exclusivity for Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials. Accordingly, your ANDA insofar as the 200 mg/40 mL Single-use Vials will be eligible for final approval 180 days after the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act.

Our decision to tentatively approve your Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials, is based upon information currently available to the agency, i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product. This decision is subject to change on the basis of new information that may come to our attention.

To reactivate your ANDA for the 200 mg/40 mL Single-use Vials strength prior to final approval, please submit a "Final Approval Request Amendment to Original #2" 90 days prior to the date you believe that this product will be eligible for final approval. Your amendment must provide a summary of the legal basis upon which you believe the ANDA should be approved, as well as:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this ANDA, or
2. a statement that no such changes have been made to the ANDA since the date of tentative approval.

Any changes in the conditions outlined in this ANDA and the status of the manufacturing and testing facilities' compliance with current good manufacturing practice (cGMP) are subject to Agency review before final approval of your Oxaliplatin Injection USP, 200 mg/40 mL Single-dose vials will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt.

In addition to the amendment requested above, the agency may request at any time prior to the final date of approval that you submit an additional amendment containing the requested information. Failure to submit either amendment may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

Your Oxaliplatin Injection USP, 200 mg/40 mL Single-use Vials, may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of a drug before the effective final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, the 200 mg/40 mL strength product will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional supplements, please contact Christina Kirby, Pharm.D., Project Manager, at 240-276-8573.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

08/07/2012

Deputy Director, Office of Generic Drugs
for Gregory P. Geba, M.D., M.P.H.