



NDA 22025/S-11

TopoTarget A/S  
U.S. Agent: Regulus Pharmaceutical Consulting, Inc.  
Attention: Alyssa Carter, Sr. Manager, Regulatory Affairs  
4840 Pearl East Circle, Suite #201E  
Boulder, CO 80301

**SUPPLEMENT APPROVAL**

Dear Ms. Carter:

Please refer to your Supplemental New Drug Application (sNDA) dated November 3, 2009, received November 4, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Totect<sup>®</sup> (dexrazoxane) for injection, 500 mg.

We acknowledge receipt of your amendments dated May 24 and August 30, 2010, January 28, February 3 and February 11, 2011.

This Prior Approval supplemental new drug application was provided to revise the carton label contents statement to align with the package insert labeling approved September 16, 2009 and to revise the container and diluent labels.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the enclosed carton, immediate container and diluent labels submitted on February 11, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22025/S-11.**" Approval of this submission by FDA is not required before the labeling is used.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Vaishali Jarral, Regulatory Project Manager, at (301) 796-4248.

Sincerely,

*{See appended electronic signature page}*

Patricia Keegan, M.D.  
Director  
Office of Drug Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURE: Carton and Container Labeling  
Diluent Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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PATRICIA KEEGAN  
03/07/2011