



NDA 22-025/S-005

**APPROVAL LETTER**

TopoTarget A/S  
c/o Regulus Pharmaceutical Consulting, Inc.  
4840 Pearl E. Circle #201 E  
Boulder, CO 80301

Attention: Alyssa Carter  
Senior Regulatory Affairs Manager, US Agent

Dear Ms. Carter:

Please refer to your supplemental new drug application dated December 19, 2008, received December 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Totect® (dexrazoxane for injection) 500 mg.

We acknowledge receipt of your submissions dated March 6, May 12, June 11 and August 12, 2009.

This supplemental new drug application provides for labeling in the new Physician's Labeling Rule format as well as proposed revisions to the package insert based on data from studies TT01, TT02 and TT04.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling submitted on August 12, 2009.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christy Cottrell, Regulatory Project Manager, at (301) 796-4256.

Sincerely,

*{See appended electronic signature page}*

Robert L. Justice, M.D., M.S.  
Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22025	SUPPL-5	TOPOTARGET AS	TOTECT (DEXRAZOXANE)

**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 JUSTICE  
09/16/2009