



ANDA 091376

Washington Food and Drug Consultants  
Attention: Gordon Johnston, MS, R.Ph.  
Director, Global Regulatory Affairs  
U. S. Agent for Fresenius Kabi Oncology Plc  
3631 Martins Dairy Circle  
Olney, MD 20832

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 30, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Topotecan Hydrochloride for Injection, 4 mg (base)/vial, packaged in Single-dose Vials.

Reference is also made to your amendments dated February 2, February 22, September 24, October 1, October 28, November 18, and November 20, 2010. We also acknowledge receipt of your correspondences dated July 28 (two submissions), July 29, July 30, August 2, August 3, August 4, August 5, August 6, August 9, August 10, August 11, August 12, August 13, August 16, August 17, August 18, August 19, and August 20, 2010, addressing the 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 the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Topotecan Hydrochloride for Injection, 4 mg (base)/vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Hycamtin for Injection, 4 mg (base)/vial, of GlaxoSmithkline.

Your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that the U.S. Patent Number 5,674,872 is method-of-use patent, and that this patent does not claim any indication for which you are seeking approval under this ANDA.

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 505-1(i).

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(1)] 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.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.  
Deputy Director  
Office of Pharmaceutical Science  
Center for Drug Evaluation and Research

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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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ROBERT L WEST

11/29/2010

Deputy Director, Office of Generic Drugs  
for Keith Webber, Ph.D.