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FDA APPROVES EXTENDED SHELF LIFE FOR
TOTECT® KIT FOR ANTHRACYCLINE EXTRAVASATION

February 6, 2012

Dear Healthcare Customer:

RE: FDA APPROVES EXTENDED SHELF LIFE FOR TOTECT® KITS WITH BATCH # 1979183/W005755/010

In order to avoid a potential shortage, Topotarget has worked with the US Food and Drug Administration (FDA) to increase the availability of Totect® Kits. Effective February 6, 2012, the FDA has approved the extension of the expiration date to 36 months for Totect® Kits with Batch # 1979183/W005755/010. Therefore, the shelf life of your kit has been extended to March 2013. The new expiration date is based on stability data that has been reviewed by the FDA and meets all mandated quality, safety and regulatory requirements in the United States.

We are asking our customer sites to over-label all affected kits currently in your inventory.

Enclosed you will find the FDA letter approving the extension of the expiration dating to March 2013 for Totect® Kits identified by Batch # 1979183/W005755/010.

Also enclosed you will find the Totect® Over-Labeling Procedure describing how to affix your date extension labels together with three clear packages containing the extension labels for your Totect® Kit. Each packet is identified as Totect® Powder labels (contains 12), Diluent Labels (contains 12), and Outer Box labels (contains 2).

The outside of your kit box should be marked with batch number 1979183/W005755/010. The vials inside this box should contain the following batch numbers:

- Totect® (dexrazoxane) for injection 500 mg/vial batch: 1979183
- Diluent for Totect® 50 mL, Diluent for Injection batch: W005755

You will note that the kit box over-label contains an “R” after the batch number and shows the new expiration date of March 2013. The vial labels have retained the original batch number (without an “R”) and also show the new expiration date of March 2013. This is intentional and is per agreement with the FDA. The labels will need to be placed on the Totect® (dexrazoxane) for injection vials, the Totect® diluent vials and the outer box to cover the original batch number and expiration date. If the batch numbers or the expiration dates on the kit box or vials do not reflect those listed above, or if the expiration dates on the enclosed stickers do not reflect the March 2013 date, please contact either Ed Lally (ELally@apricusbio.com) or Ysabella Fernando (YFernando@apricusbio.com) at 858-222-8041.

Please maintain a copy of the FDA letter approving the shelf life extension inside the Totect® Kit box. Please return the signed over-labeling procedure to Topotarget USA in the self-addressed, prepaid envelope.

To report adverse events, please call Topotarget USA at (866) 914-2922 24 hours a day / 7 days a week. Adverse events that may be related to the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, telephone, or fax:

Online: www.fda.gov.medwatch/report.htm
Regular Mail: Use postage-paid FDA Form 3500 available at:
www.fda.gov/medwatch/getforms.htm

Mail to: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787

Telephone: 1-800-332-1088
Fax: 1-800-FDA-0178

If you have any questions or need assistance with over-labeling, you may contact either Ed Lally (ELally@apricusbio.com) or Ysabella Fernando (YFernando@apricusbio.com) at 858-222-8041.

Sincerely,

Richard Martin
Vice President of Chemistry and Manufacturing

Checklist:

- ☐ Follow the Totect® Over-Labeling Procedure
- ☐ Enclose the FDA letter approving shelf life extension inside kit box
- ☐ Sign and Date Totect® Over-labeling Procedure Sheet and return in self-addressed, pre-paid envelop

Enclosures:

FDA Approval Letter
Totect® Over-Labeling Procedure
Totect® Powder Extension Labels 1979183 – Mar 2013
Totect® Diluent Extension Labels W005755 – Mar 2013
Totect® Outer Box Labels 1979183/W005755/010R – Mar 2013
Topotarget USA self-addressed, prepaid envelope