



NCCTG

NORTH CENTRAL CANCER TREATMENT GROUP

Date: March 7, 2008
To: NCCTG Primary Clinical Research Associates
From: NCCTG Research Base Pharmacy
Re: N06CA Pharmacy Procedures

Dear NCCTG Colleagues:

IMPORTANT: THIS MEMO CONTAINS INFORMATION FOR THOSE INDIVIDUALS INVOLVED IN ORDERING AND USE OF GEL AND PLACEBO FOR STUDY: N06CA, "The Use of Topical Baclofen, Amitriptyline HCl, and Ketamine (BAK) in a PLO Gel vs. Placebo for the Treatment of Chemotherapy Induced Peripheral Neuropathy: A Phase III Randomized Double-Blind Placebo Controlled Study." Please distribute this information to all appropriate individuals.

The active BAK gel to be used in this trial contains ketamine. Ketamine is classified as a schedule III controlled substance under the Federal Controlled Substances Act. If you are participating in this trial, your site must comply with state and federal regulations related to the storage, use and disposal of controlled substances.

When you place your *first order* for starter supplies of the BAK/placebo, please complete the NCCTG "Clinical Drug Order/Return Form" and include a copy of your pharmacy's Controlled Substance Registration Certificate or the Controlled Substance Registration Certificate of your principal investigator. Please note: After you receive the your first shipment, the NCCTG Registration Center will monitor your supply and contact the NCCTG operation base pharmacy to arrange for subsequent shipments as needed.

BAK/placebo will be shipped via Federal Express so that a tracking number is available to the NCCTG operation base pharmacy if needed. The NCCTG operation base pharmacy will include a copy of the NCCTG "Clinical Drug Order/Return Form" with each shipment. The individual who checks the shipment into stock should sign their name and date of receipt on the face of the order form and fax the form to the NCCTG operation base pharmacy at 507-284-3464. If this fax number is inoperable, please fax the form to 507-266-9359.

If you have expired jar(s) of BAK/placebo or unused jars at the completion of the trial, please destroy them in accordance with policies and procedures in place at your institution that relate to the destruction of pharmaceutical products and/or controlled substances.