



Date: April 11, 2008

To: NCCTG Primary Clinical Research Associates

From: Daniel Satele, N06CA Protocol Development Coordinator

Re: Continuation Phase Drug Supply and Updated Forms Packet

Dear NCCTG Colleague:

**IMPORTANT:** THIS MEMO CONTAINS INFORMATION FOR THOSE INDIVIDUALS INVOLVED IN ORDERING AND USE OF BAK GEL *for the optional continuation phase of study N06CA*. **Please distribute this information to all appropriate individuals as soon as possible.**

*After you have enrolled a patient or patients in study N06CA and anticipate activity in the optional continuation phase, please place an order for a starter supply of BAK gel. Please be sure to indicate on the order that you wish to receive the gel for use in the continuation phase. (There is no need for your site to provide the NCCTG pharmacy with a copy of your Controlled Substance Registration Certificate at this time. The pharmacy already has a copy on file.)*

The NCCTG pharmacy will attempt to minimize waste of the “open-label” BAK gel used in the continuation phase. Your site will receive a pre-determined starter supply. You will be responsible for monitoring the supply and sending re-order when you feel your supplies are inadequate.

The BAK gel will be shipped via Federal Express so that a tracking number is available to the NCCTG operation base pharmacy if needed.

Additionally, an updated forms packet is now available. The On-Study Form has been revised to collect the provider-assessed neurotoxicity evaluation data which is required to be collected at baseline per Section 4.0 of the protocol document. This new piece of information should be completed for all patients (even those who are already on study).