Dear Ms. Dhillon:


This prior approval supplemental new drug application provides for revision of the “Post-marketing Experiences” subsection of the ADVERSE REACTIONS section of the package insert to include rare cases of angioedema and anaphylactic reactions reported since approval. This submission was received electronically as Labeling Supplement- Prior Approval with final printed label (FPL) and structured product labeling (SPL).

We have completed our review of this supplemental application. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert).

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).
If you have any questions, please call Janet Jamison, Regulatory Project Manager, at (301)796-2313.

Sincerely,

{See appended electronic signature page}

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

Enclosure
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Justice
8/7/2008 02:29:54 PM