Dear Mr. Frullo:


Please also refer to your electronic mail correspondence of February 3, 2009 indicating agreement with FDA requested recommended revisions.

This “Changes Being Effected” supplemental new drug application provides for adding safe handling text to the PRECAUTIONS: Information for Patients and the HOW SUPPLIED: Directions for the Pharmacists sections as well as amending the storage statement to the USP standard definition in the HOW SUPPLIED: Stability section. Minor editorial changes were also included.

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

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text at the time of next printing. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission “SPL for approved supplement NDA 17-588/S-034”.

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, call James M. Saunders, Regulatory Project Manager, at (301) 796-0621.

Sincerely,

(See appended electronic signature page)

Robert L. Justice, M.D., M.S.
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
4/30/2009 06:02:16 PM