



NDA 20-038/S028

Berlex
15049 San Pablo Avenue
Richmond, CA 94804-0099

Attention: Anthony Bourdakis
Vice President, Regulatory Affairs

Dear Mr. Bourdakis:

Please refer to your supplemental new drug application dated February 7, 2003, received February 10, 2003, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Fludara (fludarabine) for Injection.

We acknowledge receipt of your submission dated June 5, 2003. We also acknowledge and retain your final printed labeling submitted February 26, 2002 in response to our December 3, 2001 approval letter for supplement S019.

This supplemental new drug application provides for revisions in the CLINIC PHARMACOLOGY, WARNINGS, and PRECAUTIONS sections of the labeling and was submitted in response to our Pediatric Written Request letter of November 9, 2001.

We completed our review of this supplemental application, as amended. This supplemental 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 (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this/these submission(s) should be designated "FPL for approved supplement NDA 20-038/S-028." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of DIVISION NAME and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Nicholette Hemingway, Regulatory Project Manager, at (301)

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur
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