



NDA 21-492/S-001

Sanofi-Synthelabo, Inc.  
90 Park Avenue  
New York, NY 10016

Attention: Richard Fosko  
Associate Director, Drug Regulatory Affairs

Dear Mr. Fosko:

Please refer to your supplemental new drug application dated October 2, 2002, received October 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eloxatin™ (oxaliplatin for injection).

This “Changes Being Effected in 30 days” supplemental new drug application provides for revisions to the product packaging so that the “oxali” prefix to the generic name appears in a different font color and/or size in fulfillment of Phase 4 commitment #9 from the August 9, 2002, approval letter.

Please submit final printed container labels (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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 21-492/S-001.” Approval of this submission by FDA is not required before the labeling is used.

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, HF-2  
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 Christy Cottrell, Consumer Safety Officer, at (301) 594-5761.

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Richard Pazdur  
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