DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

7997 '03 NOV -5 A9:11

Re: Eloxatin
Docket No.: 03E-0153

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,420,319, filed by Sanofi-Synthelabo, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Eloxatin, the human drug product claimed by the patent.

The total length of the regulatory review period for Eloxatin is 3,417 days. Of this time, 3,370 days occurred during the testing phase and 47 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: April 3, 1993.

   The applicant claims May 2, 1997, as the date the investigational new drug application (IND) became effective. The date provided by the applicant is the date the FDA released a clinical hold that had been placed on the application on August 16, 1993. Because that clinical hold was placed on the application more than 30 days after receipt of the IND, FDA considers the IND effective date to be April 3, 1993, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 24, 2002.

   The applicant claims July 22, 1999, as the date the new drug application (NDA) for Eloxatin (NDA 21-063) was initially submitted. However, FDA records indicate that the FDA refused to file NDA 21-063, and this NDA was ultimately withdrawn. The applicant subsequently submitted, and the FDA accepted for filing, a different NDA

03E-0153 LET 3

(NDA 21-492) on June 24, 2002. NDA 21-492 was approved for marketing on August 9, 2002.

3. The date the application was approved: August 9, 2002.

FDA has verified the applicant's claim that NDA 21-492 was approved on August 9, 2002.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Michael D. Alexander
Sanofi-Synthelabo, Inc.
9 Great Valley Parkway
Malvern, PA 19355