DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

7857 '01 AUG -3 P1:41

Lipomed, Inc.
Attention: Dr. H. Hamberger
One Broadway
Cambridge, MA 02142

AUG - 1 2001

Docket No. 00P-1621/CP1

Dear Dr. Hamberger:

This is in response to your petition filed on November 15, 2000, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Cladribine Injection 2 mg/mL, 5 mL vials (Total-Drug-Content 10 mg). The listed drug product to which you refer in your petition is Leustatin® (Cladribine) Injection, 1 mg/mL, 10 mL vials (Total-Drug Content 10 mg) manufactured by RW Johnson Pharmaceutical Research Institute.

Your request involves a change in strength (concentration) from that of the listed drug product, i.e., from 1 mg/mL to 2 mg/mL. The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Sections 505(j)(2)(C)(i) of the Act, such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the differing strength.

The Agency has determined that your proposed change in strength (concentration) raises questions of safety and effectiveness. During normal use, Cladribine is administered at doses that are often associated with severe hematologic toxicity. A doubling of the dose, which may occur if the Agency permitted the approval of a more concentrated product, could result in serious and perhaps lethal toxicity. FDA is not required to approve a change in strength under Section 505(j)(2)(C) that would introduce a heightened risk for this product. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product. If you wish to pursue the approval of this drug product, we suggest that you consult with the Division of Oncologic Drug Products at (301) 594-2473.

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If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33, and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research