CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 21055

CORRESPONDENCE

NDA 21-055

AUG 18 1999

Ligand Pharmaceuticals Incorporated
Attention: Howard T. Holden, Ph.D.
VP, Regulatory Affairs and Compliance
10275 Science Center Drive
San Diego, California 92121-1117

Dear Dr. Holden:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Targretin® (bexarotene) capsules, 75 mg

Therapeutic Classification: Priority (P)

Date of Application: June 22, 1999

Date of Receipt: June 23, 1999

Our Reference Number: NDA 21-055

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 21, 1999, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be December 23, 1999.

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products,
HFD-150
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Drug Products,
HFD-150
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, contact Amy Chapman, Project Manager, at (301) 594-5771.

Sincerely,

/S/ for 8-18-99.

Dotti Pease
Chief, Project Management Staff
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 21-055
HFD-150/Div. Files
HFD-150/A.Chapman
DISTRICT OFFICE
F/T by: Chapman-8-18-99

ACKNOWLEDGEMENT (AC)

NDA 21-055

SEP 9 1999

Ligand Pharmaceuticals, Inc.
Attention: Angeline K. Shashlo, R.Ph.
Director, Regulatory Affairs and Compliance
10275 Science Center Drive
San Diego, California 92121-1117

Dear Ms. Shashlo:

We acknowledge receipt on August 27, 1999 of your August 26, 1999 correspondence requesting a meeting to discuss the results of the draft medical officer's review and statistical review prior to the anticipated December ODAC meeting. We have concluded that the meeting is unnecessary at this time because there are no issues regarding your NDA that need to be discussed. If during the review of your NDA, an issue arises that needs discussion, we will schedule a telephone conference or meeting.

If you disagree that a meeting is not necessary at this time, we encourage you to discuss the matter with Amy Chapman, Consumer Safety Officer, of this division. If the issue can not be resolved at the division level, you may formally request reconsideration of the matter at the office level after providing the division an opportunity to review any materials you intend to rely on in an appeal to Robert Temple, M.D., Director, Office of Drug Evaluation I. A copy of any appeal should be sent to this division.

If you have any questions, contact Amy Chapman, Consumer Safety Officer, at (301) 594-5771.

Sincerely,

/S/ for 9-9-99
Robert L. Justice, M.D.
Acting Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Orig. NDA 21-055
HFD-150/Div. File
HFD-150/Johnson/Chapman/Pease/Justice/Vaccari
R/T by: Chapman-9-7-99
R/T init by: Pease-9-8-99/Johnson-9-8-99
F/T by: Chapman-9-9-99
GENERAL CORRESPONDENCE