CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-109 (17-970/S-050)

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-109

INFORMATION REQUEST LETTER

1.25.02

AstraZeneca Pharmaceuticals, LP
Attention: Laura Garcia-Davenport, MS
Associate Director, Regulatory Affairs
1800 Concord Pike, Po Box 8355
Wilmington, DE 19803-8355

Dear Ms. Davenport:

Please refer to your February 28, 2002, new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nolvadex (tamoxifen citrate) 20 mg tablets.

We also refer to your submissions dated April 9, 12, and 18, May 14, 16, and 28, June 18 and 27, and July 17, 2002.

We have completed our review and have the following concerns and requests. In an effort to capture safety information, we request an agreement from you to provide follow-up information on the girls involved in the completed study entitled " An Open-Label Trial Evaluating the Safety and Efficacy of Nolvadex (tamoxifen citrate) in the Treatment of McCune-Albright Syndrome (Study 6157US/0013)" with regard to uterine and ocular effects. Discussion with the division is encouraged to direct specific investigation options.

We request a written response within the next two weeks.

If you have any questions, call Monika Johnson, Regulatory Project Manager, at 301-827-6370.

Sincerely,

{See appended electronic signature page}

/S/

David G. Orloff, MD
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

David Orloff
7/25/02 05:49:17 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-109

AstraZeneca Pharmaceuticals LP
Attention: Laura Garcia-Davenport, MS
Associate Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

3/7/02

Dear Ms. Garcia-Davenport:

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:	Nolvadex (tamoxifen citrate) Tablets
Review Priority Classification:	Priority (P)
Date of Application:	February 28, 2002
Date of Receipt:	March 1, 2002
Our Reference Number:	NDA 21-109

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 April 30, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 1, 2002.

This application proposes to add information regarding the use of this drug in pediatrics patients with McCune-Albright Bright Syndrome. We note that this application was submitted in response to our Written Request dated April 5, 2001. note this is the day that the firm rec'd the WR

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/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6370.

Sincerely,

/S/

{See appended electronic signature page}

Monika Johnson, Pharm.D.
Regulatory Project Manager
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Monika Johnson
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