DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021344/S-033

SUPPLEMENT APPROVAL

Astra Zeneca
Attention: Jamie L. Austin, Ph.D., RAC
Regulatory Affairs Director
1800 Concord Pike
Wilmington, DE 19803

Dear Dr. Austin:

Please refer to your Supplemental New Drug Application (sNDA) dated October 10, 2016, received October 10, 2016, and your amendment dated November 7, 2016, received on November 7, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Faslodex (fulvestrant) Injection.

This Changes Being Effected supplemental new drug application provides for updated carton labeling to match the Full Prescribing Information approved under NDA 021344/S-029 on July 12, 2016.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to carton and immediate-container labels submitted on November 4, 2016 as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021344/S-033**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Pamela Balcazar, Regulatory Project Manager, at (240) 402-4203.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy Director
Division of Hematology and Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

AMNA IBRAHIM
01/24/2017