



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-080/S007

Abbott Laboratories
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, Illinois 60064-6157

Attention: Lee M. Muraoka, BSPHarm, MS
Senior Regulatory Affairs Administrator

Dear Mr. Muraoka:

Please refer to your supplemental new drug application dated September 8, 1999, received September 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ProSom (estazolam tablets).

We acknowledge receipt of your submission dated March 15, 2004.

Your submission of March 15, 2004 constituted a complete response to our November 26, 2002 action letter.

This supplemental new drug application provides for revisions to the DESCRIPTION, CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS sections of the label.

We have completed our review of this supplemental new drug application, as amended, and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 15, 2004.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Bob Rappaport
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