



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-251 / S-024
Targacept, Inc.
Attention: George R. Hemsworth, Ph.D.
200 East First Street, Suite 300
Winston-Salem, NC 27101-4165

Dear Dr. Hemsworth:

Please refer to your August 20, 2002, supplemental new drug application, received August 22, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Inversine (mecamylamine hydrochloride) Tablets, 2.5 mg.

We also acknowledge receipt of your submission dated October 16, 2002.

The supplemental application provides for (b)-----
Inversine Tablets.

We have completed the review of this supplemental application as amended, and it is approved.

Please submit final printed labeling (FPL), identical to your draft labeling (text for the package insert and container labels) in the next Annual Report.

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

If you have any questions, call Zelda McDonald, Regulatory Health Project Manager, at (301) 594-5300.

Sincerely,

{See appended electronic signature page}

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products, (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Kasturi Srinivasachar
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