DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 11 1997

TRANSMITTED VIA FACSIMILE

Anne E. Norris
Attorney
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Re: **NDA 19-640**
Humatrope (somatropin rDNA origin for injection)
MACMIS ID #5580

Dear Ms. Norris:

Reference is made to Eli Lilly and Company (Lilly's) June 11, 1997, FDA form 2253 submission for Humatrope. The materials include the following Humatrope panels:

. HG8013 Panels for AR-Quality of Life
. HG8014 Panels for AR Comprehensive
. HG8015 Panels for Children/Turners
. HG8426 Nottingham Panel w/ Fair Balance

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these materials and has determined that they are misleading in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations for the following reasons:

Presentation of Risk Information

. Panels HG8014, HG8015 and HG8426 lack fair balance because the presentation of the risk and adverse event information in a small block text on the bottom of the promotional pieces lacks prominence and is not reasonably comparable to the presentation of efficacy information.

Selective Presentation of Efficacy Information

. Panels HG8013, HG8014, and HG8426 referencing the Nottingham Health Profile findings are misleading because they fail to reveal facts material in light of the efficacy representations. The panels selectively present the positive findings and fail to provide adequate context for the study results. Lilly presents only the significant findings for two of six health related domains but fails to include the results for the four domains with non-significant findings.

. Panel HG8014 is misleading because, while Lilly selectively presents the positive findings for Humatrope's effect on HDL cholesterol, Lilly fails to present the fact that improvements in total cholesterol did not persist after three months of therapy.

DDMAC requests that Lilly immediately discontinue the dissemination and use of these materials and other promotional materials that contain similar themes. DDMAC requests that Lilly submit a written response to this letter no later than July 28, 1997, including Lilly's plan to comply with DDMAC's request.

If Lilly has further comments or issues, please contact me at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence related to this matter, please refer to MACMIS ID #5580 and the NDA number.

Sincerely,

Anne M. Reb, MS, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications