



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

IND 44,258

Food and Drug Administration
Rockville MD 20857

Genelabs Technologies, Inc.
Attention: Kerry Maurer
Senior Manager, Regulatory Affairs
505 Penobscot Drive
Redwood, California 94063

MAR 31 1999

Dear Ms. Maurer:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for dehydroepiandrosterone (DHEA).

We also refer to your January 15, 1999, request for Fast Track Drug designation submitted under section 506 of the Act.

We have reviewed your request and have concluded that it meets the criteria for Fast Track designation. Therefore, we are designating DHEA for the treatment of systemic lupus erythematosus (SLE) as a Fast Track product.

We are granting Fast Track designation for the following reasons:

1. SLE is considered a serious disease for which no adequate therapy is available currently.
2. There have been promising but inconclusive results from clinical investigations.

If you pursue a clinical development program that does not support use of DHEA for SLE, the application will not be reviewed under the Fast Track program.

If you have any questions, contact Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely yours,

John E. Hyde, Ph.D., M.D.

Deputy Director

Division of Anti-Inflammatory, Analgesic,
And Ophthalmic Drug Products, HFD-550

Office of Drug Evaluation V

Center for Drug Evaluation and Research