DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY - 4 2000

TRANSMITTED VIA FACSIMILE

Kelly Freeman
Director, Promotional Regulations and Compliance
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

RE: IND[ ]
MACMIS ID #8966

Dear Ms. Freeman:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified certain promotional activities by Eli Lilly and Company (Lilly) that are in violation of the Federal Food, Drug, and Cosmetic Act (Act). Specifically, Lilly is promoting its investigational new drug, IC351, as safe or effective at its promotional exhibit booth at the 95th annual meeting of the American Urological Association (AUA) in Atlanta.

Section 21 CFR 312.7 states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. Your exhibit booth at AUA includes convention panels describing the safety and effectiveness of IC351, an investigational treatment for erectile dysfunction. For example, you present claims such as "[i]n this study of IC351, dosages of 5 mg and 10 mg appeared to offer an optimal combination of efficacy and safety."

Moreover, one of your representatives explained to visitors to the exhibit booth that IC351's mechanism of action is more specific towards a certain receptor compared to sildenafil's mechanism of action. Your representative further explained that this specificity eliminated certain side effects associated with sildenafil. These claims concerning the safety or effectiveness of your investigational product are also violative.

Per our telephone conversations, we understand that the booth is no longer in use.

In order to address these objections, DDMAC recommends that Lilly take the following actions:

1. Immediately discontinue the use all other promotional materials and activities for IC351 that contain the same or similar violations.

2. Provide to DDMAC, in writing, your intent to comply with #1 above. Your response should be received by May 18, 2000.

3. This response should include a list of all similarly violative promotional materials and your method for discontinuing their use.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #8966 in addition to the NDA number.

Sincerely,

/S/

Mark W. Askine, R.Ph.
Branch Chief (Acting)
Division of Drug Marketing,
Advertising, and Communications