DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

NOV 19 1998

Charles R. Perry, Jr.
Director, Pharmaceutical Communications
and Compliance Regulatory Liaison
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

RE: NDA # 50-675
Ceclor CD (cefaclor extended release tablets)
MACMIS ID # 7263

Dear Mr. Perry:

The Division of Drug Marketing, Advertising, and Communications, (DDMAC) as part of its routine monitoring and surveillance program, has reviewed material that is used to promote Eli Lilly and Company's (Lilly) product, Ceclor CD. This material is dosing card CD183A0898, submitted under cover of Form FDA 2253. DDMAC finds the dissemination of the dosing card to be in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and its implementing regulations.

Specifically, DDMAC objects to the following:

Dosing card CD 183A0898 is misleading because it fails to provide any balancing information about the adverse events, risks, warnings, or precautions associated with the use of Ceclor CD. For example, the dosing card fails to include the most common adverse events (headache (4.9%), rhinitis (3.8%), diarrhea (3.8%), nausea (3.4%), etc.); and information that, prior to prescribing Ceclor CD, practitioners should determine whether the patient has had previous hypersensitivity reactions to cefaclor, cephalosporins, penicillins, or other drugs. The card states the indications, the dosing frequency, and the duration of therapy for the indicated conditions. These statements are clear representations about the use of the product, and therefore, the dosing card is considered promotional labeling that requires, on its face, a statement of risks in addition to an accompanying PI.

In order to address this violation, DDMAC recommends that Lilly take the following actions.

1. Immediately discontinue the use of the aforementioned material and any other promotional materials for Ceclor CD that contain the same or similar violation; and

2. Provide a written response to DDMAC of your intent to comply with the above request, a list of promotional materials containing the misleading presentations that will be discontinued, and the date of discontinuation.

Lilly's response should be received no later than 10 business days from the issue date of this letter. If Lilly has 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-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

DDMAC reminds Lilly that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID # 7263.

Sincerely,

Jo Ann Spearmon, Pharm.D., M.P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications