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Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285
U.S.A.

Phone 317 276 2000

March 8, 2001

[redacted]

Mr. Raymond Mlecko
Acting District Director
1560 East Jefferson Avenue
Detroit, Michigan 48207

RE: Eli Lilly and Company 483 Response and Interim Warning Letter Response

Dear Mr. Mlecko:

During the period of January 29 – February 9, 21, 22, 23, 2001, Investigators Patricia A. Cochran, Thomas J. Arista and Jeffrey A. Sommers conducted a Preapproval Inspection for [Zyprexa ® (olanzapine) Rapid Action IntraMuscular NDA 21-253] and a general GMP inspection of the sterile pharmaceutical manufacturing operation located at 1555 S. Harding Street, Indianapolis, Indiana.

A Form FDA 483 was issued at the conclusion of the inspection. A Warning Letter dated March 2, 2001 was received on March 6, 2001.

We take very seriously each of the observations raised in the 483 and Warning Letter. The content of each have been reviewed in detail with our most senior management. We are committed to aggressively completing the actions described in our response. We have provided details of actions including protocols, procedures and supporting documents as attachments.

In addition, we fully realize that the expectations apply not only to all products that are aseptically filled at this facility, but also to all of our locations. We recognize the need for a proactive, comprehensive, and systematic evaluation and implementation at all Lilly sites. We are addressing this need with three parallel efforts:

1. The FDA 483 observations and responses have been shared with all Lilly sites. The Corporate Quality Assurance group will work with the Quality Control Unit at each site to assess the impact of these observations across their operations and to complete associated site action plans on an aggressive timeline.

2. Several of your observations revolved around how we document our practices. Our Corporate Quality Assurance Group will direct an evaluation of the Lilly Corporate Quality Policies and their implementation through local procedures at all sites. We will hire outside consultant(s) to assist in the conduct of this evaluation.

3. We recognize the need for a comprehensive strategy governing the revalidation and requalification of facilities and equipment. We are creating a senior position to focus on the development and implementation of a more robust approach for re-validation and requalification across our parenteral facilities. In addition, we are hiring outside consultant(s) to conduct an evaluation of our current practices and to assist us in this endeavor.

We have confirmed a meeting to be held on March 15, 2001 at the FDA Detroit District Office between FDA representatives and appropriate personnel from Lilly to discuss the details of our responses and to address any questions you might have after you have completed your review. Among other things, we would like to discuss any further reports the Agency may wish to see regarding this matter.

Eli Lilly and Company is committed to resolving each and every concern which the agency has relating to this inspection. Lilly believes its response satisfactorily addresses the concerns voiced by the investigators. If appropriate, we will provide a further response to you following our meeting. We ask that this response be provided with any request pursuant to the Freedom of Information Act.

Sincerely,

ELI LILLY AND COMPANY

Scott A. Canute
Vice President Manufacturing
Eli Lilly and Company

cc: Thomas J. Arista
Patricia A. Cochran
John P. Dempster
David M. Kaszubski
Judith A. Putz
Jeffrey A. Sommers