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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, RM. 1061
Rockville, Maryland 20852

Re: Docket No. 03D-0317, Federal Register: July 28, 2003 (Volume 68, Number 144, Page 44345-44346)

Dear Dr. Jenkins and Dr. Yetter,

Eli Lilly and Company appreciates the ability to respond to the draft guidance on Good Review Management Principles for PDUFA products in the attached comments. We feel the implementation of good review management is key to the success of PDUFA goals. We have also reviewed and support the comments provided by both the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America.

This response is organized as three sections including an Executive Summary followed by general comments on the content and then very specific line-by-line comments and suggestions with rationale.

Eli Lilly and Company agrees with both the spirit and goals of the GRMP initiative and believe this guidance serves as an important foundation for meeting these goals.

Sincerely,

ELI LILLY AND COMPANY

Timothy R. Franson, M.D.
Vice President
Global Regulatory Affairs

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