DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

(b) (4)

AMENDED WRITTEN REQUEST

Eli Lilly and Company
Attention: Dr. Gregory Brophy
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Brophy:

Reference is made to the pediatric Written Request issued November 16, 2006. We also refer to our correspondence dated August 28, 2009 wherein we agreed that no additional communication requesting an amendment to the timeframe for reporting as outlined in the Written Request would be needed prior to October 1, 2009.

This Amended Written Request memorializes our previous agreement on the timeframe for reporting. That timeframe is amended from October 1, 2009 to August 20, 2017. Note that any potential future changes to the Written Request must be in the form of a written amendment to the Written Request. The remainder of the Written Request remains as follows (no additional changes have been made):

This Written Request contains a mixture of requirements (failure to fulfill these would result in denial of exclusivity) *and* advice. We have highlighted formal requirements to make this distinction clear.

The Food and Drug Administration (FDA) is making a formal Written Request, pursuant to Section 505A of the Federal Food, Drug, and Cosmetics Act, that you submit information from the studies outlined below to provide guidance for the use of tadalafil (b) (4)

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Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
[redacted]	GI-1	ELI LILLY CO	CIALIS (TADALAFIL)

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/s/

ROBERT TEMPLE
04/12/2010