



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Rockville, MD 20857

WRITTEN REQUEST

(b) (4)

Eli Lilly and Company
Attention: Bryan Boggs, Pharm.D.
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Boggs:

Reference is made to your June 9, 2006 Proposed Pediatric Study Request submitted to (b) (4) for tadalafil.

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

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this page is the manifestation of the electronic signature.**

/s/

Robert Temple
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