

Updegraff, Kimberly

From: Updegraff, Kimberly
Sent: Thursday, November 06, 2008 1:19 PM
To: KUNTZ_MATT@LILLY.COM
Cc: Updegraff, Kimberly; Kiedrow, Keith
Subject: NDA 22-173 (Zyprexa depot) - Info request

Dear Matt,

Hello. I am a project manager working with Keith Kiedrow in the Division of Psychiatry Products and I have the following request from the review team concerning NDA 22-173.

Please provide scientific justification for the modification of the title, information, and dosing regimens listed in Table 1 entitled "Approximate Dose Correspondence at Steady State Between Oral Zyprexa and Zyprexa Tradename" of the original NDA labeling to the new version submitted in your response to our 2/25/08 NA letter.

In the most recent version (12 June 2008) of labeling that you submitted, you changed Table 1 entirely with a new title of "Recommended Dosing Between Oral ZYPREXA and ZYPREXA Relprev". In contrast to the original Table 1, the information in this new version of Table 1 does not appear to be supported by data in your development program, nor is it adequately justified. Please provide an explicit evidence-based justification to support your modification of labeling with the replacement of the original Table 1 with the new Table 1 regarding "Starting" and "Maintenance" doses in your most recent version of labeling.

Please respond by 11 November 2008.

Sincerely,

Kim

Kimberly Updegraff, R.Ph., M.S.
Regulatory Project Manager
Division of Psychiatry Products
Center for Drug Evaluation and Research, FDA
Office of Drug Evaluation
Phone: (301)796-2201

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

/s/

Kimberly Updegraff
11/6/2008 01:26:59 PM
CSO

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		REQUEST FOR CONSULTATION		
TO (Division/Office): Office of Surveillance and Epidemiology (OSE) attention: Mary Dempsey		FROM: HFD-130 (Division of Psychiatry Products); Keith Kiedrow		
DATE August 5, 2008	IND NO.	NDA NO. 22-173	TYPE OF DOCUMENT Risk Management Plan	DATE OF DOCUMENT June 13, 2008
NAME OF DRUG Zyprexa (olanzapine) Depot Injection		PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE October 13, 2008
NAME OF FIRM: Lilly				
REASON FOR REQUEST				
I. GENERAL				
<input type="checkbox"/> NEW PROTOCOL <input type="checkbox"/> PROGRESS REPORT <input type="checkbox"/> NEW CORRESPONDENCE <input type="checkbox"/> DRUG ADVERTISING <input type="checkbox"/> ADVERSE REACTION REPORT <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION <input type="checkbox"/> MEETING PLANNED BY <input type="checkbox"/> PRE--NDA MEETING <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> SAFETY/EFFICACY <input type="checkbox"/> PAPER NDA <input type="checkbox"/> CONTROL SUPPLEMENT <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER <input type="checkbox"/> FINAL PRINTED LABELING <input type="checkbox"/> LABELING REVISION <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE <input type="checkbox"/> FORMULATIVE REVIEW OTHER (SPECIFY BELOW):				
II. BIOMETRICS				
STATISTICAL EVALUATION BRANCH		STATISTICAL APPLICATION BRANCH		
<input type="checkbox"/> TYPE A OR B NDA REVIEW <input type="checkbox"/> END OF PHASE II MEETING <input type="checkbox"/> CONTROLLED STUDIES <input type="checkbox"/> PROTOCOL REVIEW <input type="checkbox"/> OTHER (SPECIFY BELOW):		<input type="checkbox"/> CHEMISTRY REVIEW <input type="checkbox"/> PHARMACOLOGY <input type="checkbox"/> BIOPHARMACEUTICS <input type="checkbox"/> OTHER (SPECIFY BELOW):		
III. BIOPHARMACEUTICS				
<input type="checkbox"/> DISSOLUTION <input type="checkbox"/> BIOAVAILABILITY STUDIES <input type="checkbox"/> PHASE IV STUDIES		<input type="checkbox"/> DEFICIENCY LETTER RESPONSE <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS <input type="checkbox"/> IN-VIVO WAIVER REQUEST		
IV. DRUG EXPERIENCE				
<input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP		<input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE <input type="checkbox"/> POISON RISK ANALYSIS		
V. SCIENTIFIC INVESTIGATIONS				
<input type="checkbox"/> CLINICAL		<input type="checkbox"/> PRECLINICAL		
COMMENTS/SPECIAL INSTRUCTIONS: The division of Psychiatry Products would like to consult OSE on the following topic – the risk management plan for NDA 22173, Zyprexa Depot Injection, for the treatment of schizophrenia. Lilly has resubmitted as of June 13, 2008 in response to our February 25, 2008 NA letter. The RMP incorporates a registry that will serve as a way of monitoring the incidence of what has been termed by our Division as “excessive sedation events”. Please review the RMP and provide recommendations as appropriate. Link to the NDA submission in the EDR - \\FDSWA150\NONECTD\N22173\N_000\2008-06-13. I have also attached the RMP pulled from that submission and attached it to this consult (although it is more easily navigable from the EDR submission itself). Let me know if you have any questions/concerns. Thanks!				
SIGNATURE OF REQUESTER Keith Kiedrow, Pharm.D. Regulatory Project Manager 301-796-1924 keith.kiedrow@fda.gov		METHOD OF DELIVERY (Check one) <input type="checkbox"/> MAIL <input checked="" type="checkbox"/> HAND		

125 pages of proposed RMP has been withheld in full immediately following this page as B4 CCI/TS