

- iii. Procedures for reconstitution and proper injection technique
 - iv. Appropriate monitoring of patients for early recognition of somnolence and other symptoms of a PDSS event
 - v. Providing patient tools that will be available for distribution to patients (e.g., patient take-away card, wristband, patient brochure, and patient DVD)
 - vi. Appropriate documentation of adverse events
 - c. The sponsor will maintain a list of the healthcare settings who have obtained the certification, and provide the list to those needing to verify that healthcare settings have obtained the required certification.
 - d. Healthcare settings will be recertified periodically, at a specified interval. We suggest the training and recertification plan be brief and made available using multiple methods to increase participation (e.g., web-based, in-person, and print materials).
3. A plan to ensure that the drug is dispensed to patients with documentation of the following safe use conditions under 505-1 (f) (3)(D):

The prescriber must document that they:

- a. have enrolled each patient in a program by obtaining, at the time of the first prescription and on a specific periodic schedule thereafter, a signed physician-patient agreement form that documents safe use conditions including:
 - i. patients being prescribed Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension have been counseled about the benefits and risks, particularly the risk of PDSS
 - ii. patients understand the need to be observed at the healthcare facility by a healthcare professional for at least 3 hours post injection
 - iii. patients understand that they need to be accompanied to and from the healthcare facility and not drive or operate heavy machinery for the remainder of the day of injection
 - iv. patients agree to contact their prescriber if symptoms of PDSS develop
 - v. patients are provided the Medication Guide
 - vi. will provide a copy of the completed enrollment form to the sponsor.

Healthcare setting staff or prescriber must document that:

- b. Patients have been monitored for sedation or other symptoms of PDSS in a controlled environment. Monitoring should be continuous for at least 3 hours after injection. Patients must be evaluated prior to being discharged. Monitoring of vital signs and cognitive function must be performed after each injection. For each injection, the following information must be recorded and submitted to the sponsor by the prescriber:
 - i. injection date and time
 - ii. dose
 - iii. verification that patient was accompanied by a caregiver
 - iv. concomitant medication use, including over the counter medications
 - v. verification that the patient left the facility absent signs and symptoms of olanzapine overdose after receiving the Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension injection

- vi. any report of a PDSS event since the previous Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension injection
- c. A specific data collection form to be developed by the sponsor and disseminated to the certified prescribers and certified healthcare facilities to collect specific data of interest and to document condition of safe use.

Implementation system: The REMS must include an implementation system to monitor and evaluate the implementation of the elements to assure safe use (outlined above) required under 505-1(f)(3)(B), (C), and (D) by parties in the healthcare system responsible for their implementation. Include a plan to address any findings of inadequate implementation of these elements to assure safe use.

The Implementation System must include:

1. A database of all certified prescribers, healthcare settings, and patients, as well as a database of the completed data forms. The database should also link the reported adverse events of interest to the enrolled patient and reporting certified facilities/prescribers.
2. A specific adverse event (AE) form to be developed by the sponsor and disseminated to the certified prescribers and certified healthcare facilities to report specific adverse events of interest that occur in association with use of Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension, including known or suspected PDSS events. The AE form must include, at a minimum, the following information:
 - a. narrative summary of the AE, including signs and symptoms of any event (including 1. sedation/somnolence, 2. delirium/confusion/disorientation/or other cognitive impairment, 3. ataxia or other problems with movement, 4. dizziness, or 5. seizure) and a detailed timeline of the course of events related to injection.
 - b. demographic characteristics of the patient (age, gender, race, height, weight, medical conditions, geographical location)
 - c. Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension dose
 - d. type and timing of interventional treatment or therapy administered
 - e. outcome of the AE
 - f. concomitant medications prior to and at the time of AE occurrence
3. A plan to monitor distribution data and prescription data to ensure that Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension is only prescribed, dispensed, and administered by the certified entities.
4. A plan to monitor the dispensing facilities to ensure they are dispensing Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension to facilities and providers only after assurance of safe use conditions. Such plan should, at a minimum, include periodic audits of the certified healthcare settings.

Timetable for Assessments: The proposed REMS must include a timetable for assessments that shall be no less frequent than every 6 months for the first year and annually thereafter, after the REMS is approved. We recommend that you specify the interval that each assessment will cover and the planned date of submission to the FDA of the assessment. We recommend that assessments be submitted within 60 days of the close of the assessment interval.

Each assessment must assess the extent to which the elements to assure safe use of your REMS are meeting the goals of your REMS and whether the goals or elements should be modified.

We suggest that your proposed REMS submission include two parts: a “Proposed REMS” and a “REMS Supporting Document.” Attached is a template for the Proposed REMS that you should complete with concise, specific information (see Appendix A). Include information in the template that is specific to your proposed REMS for Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension. Additionally, all relevant proposed REMS materials including educational and communication materials should be appended to the proposed REMS. Once FDA finds the content acceptable and if the drug is approved, we will include these documents as an attachment to the approval letter that includes the REMS.

The REMS Supporting Document should be a document explaining the rationale for each of the elements included in the proposed REMS (see Appendix B).

Information necessary for the assessment should include, but may not be limited to, the following:

1. A narrative summary and analysis of all cases of PDSS based upon data provided by prescribers and healthcare site staff reported on the special monitoring form or information reported spontaneously to the sponsor. Cases of PDSS would include those that meet the criteria generally in the draft case definition that you included in your risk management plan submitted June 13, 2008, listed under Appendix C.
2. An assessment of healthcare provider and patient understanding of conditions of safe use of Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension; i.e., the results of surveys administered to prescribers, healthcare settings staff, and patients. This will include any known data about prescribers, infusion site staff, and patients who refuse to participate in the surveys, any known data about survey participants considered “lost” (drop-outs), basic demographics of patients completing questionnaires (age, gender, region), and prescribers (specialty, region, number of patients on Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension) compared to those not surveyed.
3. Reports on the status of the training and certification program for prescribers and clinical administration sites including:
 - a. the extent to which prescribers who have not been trained and certified are prescribing Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension,
 - b. the extent to which healthcare settings that have not been certified are administering Zyprexa TRADENAME (olanzapine) for Extended Release Injectable Suspension.
4. Reports on adherence to the conditions of safe use indicated in the label including evaluations of signs and symptoms consistent with PDSS and the corresponding actions taken. Also include verification that patient was accompanied by a caregiver upon leaving the facility.
5. Reports on the periodic assessments of the distribution and dispensing of the Medication Guide in accordance with 21 CFR 208.24.
6. A report on periodic audits of the certified healthcare settings.

7. Based on the information provided, an assessment and conclusion of whether the REMS is meeting its goals, and whether modifications to the REMS are needed.

The Other Relevant Information section of your REMS Supporting Document should also include a thorough explanation of the rationale for and supporting information about the methodology that will be used to determine compliance with adherence to safe use conditions.

The Other Relevant Information section of your REMS Supporting Document should include a thorough explanation of the rationale for and supporting information about the survey protocols.

Please include all survey methodology including but not limited to:

- Sample size and confidence associated with the sample size
- How the sample will be determined (selection criteria)
- The expected number of prescribers, injection administration site staff, and patients to be surveyed annually
- How the surveys will be administered
- How often the surveys will be administered
- Explain controls used to minimize bias
- Explain controls used to compensate for the limitations associated with your methodology

Provide any background information on testing survey questions and their correlation to the educational materials, and explain what will be done with the resulting data from the surveys. Append all survey instruments (questionnaires and moderator's guide). Provide any background information on testing survey questions and the correlation to the training/educational materials, and explain what will be done with the resulting data from the surveys.

The Other Relevant Information section of your REMS Supporting Document should also include a thorough explanation of the rationale for and supporting information about the methodology that will be used to determine compliance with adherence to safe use conditions.

If you do not submit electronically, please send 5 copies of your proposed REMS as an amendment to your application. Prominently identify the proposed REMS submission with the following wording in bold capital letters at the top of the first page of the submission:

PROPOSED REMS FOR NDA 22-173

On the first page of subsequent submissions related to the proposed REMS, prominently identify the submission with the following wording in bold, capital letters at the top of the first page:

NDA 22-173 / PROPOSED REMS - AMENDMENT

Office of Clinical Pharmacology

We request you adopt the following dissolution method and specifications –

1% Sodium Lauryl Sulfate in USP buffer pH 6.8 medium using USP Apparatus 4 (or Ph.Eur.2.9.3 Flow-Through Apparatus) at 3 ml/min flow rate.

210 mg:

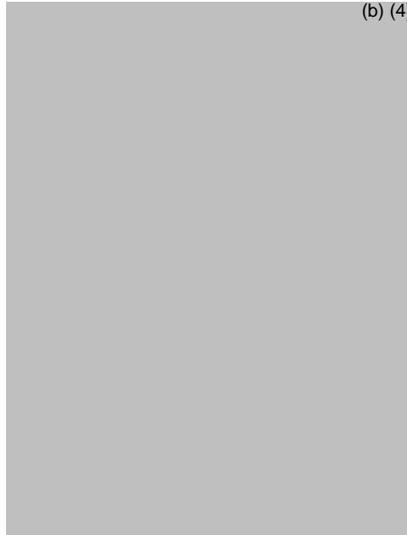
%released at 30 min
% released at 2 hrs
% released at 8 hrs

300 mg:

%released at 30 min
% released at 2 hrs
% released at 8 hrs

405 mg:

%released at 30 min
% released at 2 hrs
% released at 8 hrs



Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA guidance for industry *Formal Meetings With Sponsors and Applicants for PDUFA Products*, (<http://www.fda.gov/cder/guidance/2125fnl.htm>).

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Keith Kiedrow, Pharm.D., Senior Regulatory Project Manager, at (301)796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Labeling and Appendices A-C

Appendix A- REMS Template

<<If you are not proposing to include one of the listed elements, include a statement that the element is not necessary.>>

Application number TRADE NAME (DRUG NAME)

Class of Product as per label

Applicant name

Address

Contact Information

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

(b) (4)



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/s/

Thomas Laughren
12/15/2008 04:05:51 PM

Risk Evaluation and Mitigation Strategy (REMS) Memorandum

**U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE of New Drugs
DIVISION of Psychiatry Products**

NDA: 22-173
Product: TRADENAME (olanzapine) for Extended Release Injectable Suspension
SPONSOR: Eli Lilly and Company
FROM: Thomas P. Laughren, M.D.
DATE: December 13, 2008

Title IX, Subtitle A, Section 901 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amends the Federal Food, Drug, and Cosmetic Act (FDCA) to authorize FDA to require the submission of a REMS if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)). Section 505-1(a)(1) provides the following factors:

- (A) The estimated size of the population likely to use the drug involved;
- (B) The seriousness of the disease or condition that is to be treated with the drug;
- (C) The expected benefit of the drug with respect to such disease or condition;
- (D) The expected or actual duration of treatment with the drug;
- (E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug;
- (F) Whether the drug is a new molecular entity (NME).

After consultations between the Office of New Drugs and the Office of Surveillance and Epidemiology, we have determined that a REMS that includes elements to assure safe use is necessary for TRADENAME (olanzapine) for Extended Release Injectable Suspension) to ensure that the benefits of the drug outweigh the risks of a serious syndrome characterized by Central Nervous System depression associated with a spectrum of symptoms consistent with olanzapine overdose classified as “Post-injection Delirium/Sedation Syndrome” (PDSS) identified during the NDA review. As of May 31, 2008, a total of 29 PDSS events were identified in 28 patients during TRADENAME (olanzapine) for Extended Release Injectable Suspension clinical trials (one patient experienced two events). Based on more than 40,000 TRADENAME (olanzapine) for Extended Release Injectable Suspension injections given to 2,054 patients in clinical trials through May 31, 2008, PDSS events have occurred in approximately 0.07% of injections or 1.4% of patients.

Furthermore, a Medication Guide is necessary for patients and caregivers to understand the risk of PDSS, in addition to the risks of hyperglycemia, hyperlipidemia, and weight

gain associated with all dosage forms of olanzapine. In reaching this determination, we considered the following:

- A. The number of patients with schizophrenia in the United States is estimated to be about 3 million. The number of patients diagnosed with schizophrenia requiring injectable therapy (e.g., those who are not compliant with oral treatment) is estimated to be less than 300,000.
- B. Schizophrenia is a major psychiatric illness, which if left untreated, results in enormous personal, family, and social disability.
- C. Use of TRADENAME (olanzapine) for Extended Release Injectable Suspension to treat schizophrenia results in better control of symptoms, decreased hospitalizations, and return to more normal function.
- D. The expected duration of therapy with TRADENAME (olanzapine) for Extended Release Injectable Suspension is indefinite and may be lifelong, with patients receiving injections every two or four weeks depending on doses.
- E. The most serious acute risk associated with the use of TRADENAME (olanzapine) for Extended Release Injectable Suspension is PDSS. In addition, there are other risks associated with the use of olanzapine including increased mortality and increased risk of stroke in elderly patients with dementia-related psychosis, neuroleptic malignant syndrome, hyperglycemia, hyperlipidemia, weight gain, tardive dyskinesia, orthostatic hypotension, seizures, impaired cognitive and motor function, and hyperprolactinemia.
- F. Olanzapine is not a new molecular entity.

In accordance with section 505-1 of the FDCA, as one element of a REMS, FDA may require the development of a Medication Guide as provided for under 21 CFR Part 208. Pursuant to 21 CFR Part 208, FDA has determined that TRADENAME (olanzapine) for Extended Release Injectable Suspension poses a serious and significant public health concern requiring the distribution of a Medication Guide. The Medication Guide is necessary for patients' safe and effective use of TRADENAME (olanzapine) for Extended Release Injectable Suspension. FDA has determined that TRADENAME (olanzapine) for Extended Release Injectable Suspension is a product that has serious risks (relative to benefits) of which patients should be made aware because information concerning the risks could affect patients' decisions to use, or continue to use TRADENAME (olanzapine) for Extended Release Injectable Suspension. FDA has also determined that TRADENAME (olanzapine) for Extended Release Injectable Suspension is a product for which patient labeling could help prevent serious adverse events.

The elements of the REMS will be a Medication Guide, elements to assure safe use, including that TRADENAME (olanzapine) for Extended Release Injectable Suspension will only be prescribed by prescribers who are specially certified (505-1(f)(3)(A)), is

administered only in healthcare settings that have been specially certified (505-1(f)(3)(B)), and given to patients that have documentation of safe-use conditions (505-1(f)(3)(D)), an implementation system, and a timetable for submission of assessments of the REMS.

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of New Drugs

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/s/

Thomas Laughren
12/13/2008 01:50:35 PM
MEDICAL OFFICER

Kiedrow, Keith

From: Greeley, George
Sent: Friday, December 12, 2008 3:22 PM
To: Kiedrow, Keith
Cc: Mathis, Lisa
Subject: NDA 22-173 Zyprexa (olanzapine depot injection)

Importance: High

Hi Keith,

The Zyprexa (olanzapine depot injection) partial waiver/deferral/plan was reviewed by the PeRC PREA Subcommittee on October 29, 2008. The Division recommended a partial waiver because disease/condition does not exist in children and a deferral because the product is ready for approval in adults. The PeRC agrees with the Division to grant a partial waiver/deferral/plan for this product.

In addition, the PeRC has requested that the approval letter also reflect the partial waiver granted for this product.

Thank you.

George Greeley
Regulatory Health Project Manager
Pediatric and Maternal Health Staff
Office of New Drugs
FDA/CDER
10903 New Hampshire Ave.
Bldg #22, Room 6467
Silver Spring, MD 20993-0002
301.796.4025

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/s/

Keith Kiedrow
12/15/2008 07:58:38 AM
CSO



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-173

Lilly Pharmaceuticals
Attention: Matt Kuntz, Regulatory Scientist, US Regulatory Affairs
Lilly Corporate Center
DC 2543
Indianapolis, IN 46285

Dear Mr. Kuntz:

Please refer to your New Drug Application (NDA 22-173) submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Olanzapine Long Acting Injection, 210 mg, 300 mg, 405 mg/vial.

We also refer to the teleconference meeting between representatives of your firm and the FDA on October 27th, 2008. The purpose of the meeting was to discuss and clarify the submitted proprietary names for NDA 22-173, Olanzapine Long Acting Injection.

The official minutes of that meeting are enclosed. You are responsible for notifying us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Daniel Brounstein, Regulatory Project Manager, at (301) 796-0674.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPH
Director
Division of Medication Error Prevention and
Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Enclosure

MEMORANDUM OF MEETING MINUTES

MEETING DATE: 10/27/2008
TIME: 3:30 – 4:00 pm, EST
LOCATION: Teleconference, WO Bldg 22, RM 4270
APPLICATION: NDA 22-173
DRUG NAME: Olanzapine long acting injection
TYPE OF MEETING: Request for Information / Clarification

MEETING CHAIR: Carol Holquist

MEETING RECORDER: Daniel Brounstein

FDA ATTENDEES:

Daniel Brounstein, Regulatory Project Manager, OSE
Cheryl Campbell, Regulatory Project Manager Team Leader, OSE
Jodi Duckhorn, Patient Labeling and Education Reviewer Team Leader, DRISK/OSE
Brian Gordon, Social Scientist, DRISK/OSE
Carol Holquist, Director, DMEPA/OSE
Denise Toyer, Deputy Director, DMEPA/OSE
Todd Bridges, Team Leader, DMEPA/OSE
Deveonne Hamilton-Stokes, Safety Evaluator, DMEPA/OSE
David Claffey, Chemist, DPA I/ONDQA I
Gwen Zornberg, Medical Officer Team Leader, DPP/OND
Phuong Nina Ton, Regulatory Project Manager, OSE
Millie Wright, Regulatory Project Manager, OSE
Marlene Hammer, Regulatory Project Manager, OSE

ELI LILLY:

Matt Kuntz, Regulatory Scientist, US Regulatory Affairs
Gregory T Brophy, Director, US Regulatory Affairs
Robert E Lee Jr, Asst General Patent Counsel
Robert A Distefano, Zyprexa Marketing, US Affiliate
Michael B Mason, Zyprexa Global Product Development Team Leader
Holland C Detke, Clinical Research Scientist, Zyprexa Global Product Development
Elizabeth Brunner, Medical Advisor, Global Patient Safety
Mary P Stickelmeyer, Research Advisor, Formulation & Process Development

BACKGROUND:

DMEPA objected to the Applicant's proposed proprietary name, Zyprexa Relprev, because it contained the USAN stem '-rev.' Additionally, DMEPA noted that the modifier was ambiguous because it has no recognized meaning among healthcare practitioners. This product is a long acting intramuscular injection of olanzapine. Lilly, currently markets an immediate release intramuscular injection of olanzapine. DMEPA's review stated that the modifier Relprev will not communicate the differences between the immediate release formulation and the long acting

formulation. Subsequently, the Applicant submitted a rebuttal to address DMEPA's concerns. DMEPA requested this teleconference to clarify points listed in Lilly's rebuttal.

MEETING OBJECTIVES:

- Discuss the Relprev rebuttal in detail
- Discuss alternate names the Applicant submitted
- Discuss if the Applicant has conducted any studies among healthcare professionals to gather information on what is a better naming convention for the proposed Zyprexa product

DISCUSSION POINTS:

1. Clarification of Issues identified in the Zyprexa Relprev rebuttal:

a. Relprev is Ambiguous as a modifier

DMEPA noted that Relprev was ambiguous and has no recognized meaning to healthcare practitioners. The Applicant stated that the proposed modifier Relprev does not have any specific meaning and that they would educate practitioners that it is synonymous with the long-acting formulation. DMEPA indicated that the proposed modifier does not communicate to healthcare practitioners the differences between the intramuscular immediate release formulation of Zyprexa and the intramuscular long-acting formulation, Zyprexa Relprev. Moreover, education is a low leverage approach to addressing this potential confusion.

The Applicant's rebuttal referred to the product Risperdal Consta as a product that uses an ambiguous modifier. However, when Risperdal Consta was introduced there was no Risperdal immediate release injectable formulation on the market. Thus, prescribers could omit the Consta modifier and the injectable long-acting formulation would still be administered. In contrast, there is already a Zyprexa immediate release formulation on the market. Thus, omission of the modifier could result in the immediate release formulation being administered instead of the Zyprexa Relprev dose. Although, a large number of the Zyprexa immediate-release vials would be needed to obtain a dose of Zyprexa Relprev, this type of medication error has occurred in the past with other products. There is always a potential for any modifier to be omitted; however, in the Zyprexa product line this could result in the wrong injectable formulation being administered. DMEPA explained that the Applicant has a higher hurdle to overcome in the naming of this product because the chosen name needs to communicate to HCPs the differences between the immediate release and long acting formulations.

DMEPA elaborated that providers tend not to know about new modifiers introduced into the market, and fill prescriptions based on what's on their shelf or what is familiar. DMEPA asserted that the best way to minimize confusion when expanding a product line is ensure that the product characteristics are distinctly different from other products within the line. Additionally, DMEPA noted that the Applicant should not solely be focused on the omission of the modifier, because there are other failure modes that can occur.

The sponsor noted that a Risk Evaluation and Mitigation Strategy (REMS) will be put into place for this product which would restrict writing for olanzapine long-acting injection for patients outside of the REMS. The sponsor believes that the REMS would help reduce medication errors. DMEPA agreed that this information will be taken into consideration for any future proprietary names proposed, but the “Relprev” proprietary name was still unacceptable due to the use of the USAN Stem “rev.”

b. USAN STEM Clarification

DMEPA maintains their objection to the proprietary name Zyprexa Relprev because it contains the USAN stem –rev. The USAN Council has designated the stem ‘-rev’ to indicate a drug that is a therapeutic virus. Use of the –rev stem for Zyprexa Relprev, a psychotropic drug is inconsistent with the USAN Council’s designation. USAN stems are reserved for established names and therefore DMEPA objects to the use of stems in proprietary names, especially when they are used in a manner that is contradictory to the USAN Council’s definition.

Although, the Applicant included in their rebuttal, examples of currently marketed products that contain the letters ‘rev,’ DMEPA clarified that these letters are acceptable to use if the letters are at the beginning or middle of the proprietary name. The letters ‘rev’ are only considered a USAN stem if they are used at the end of a proprietary name (as with *Relprev*). The USAN stem list specifically identifies the position of the letters within the drug name.

The sponsor asked DMEPA whether a variant spelling of “Relprev would still be viewed as using the USAN stem (i.e., adding a second v at the end of the name—Relprevv). DMEPA responded that changing the proposed proprietary name so that “rev” was not the suffix would cause the proprietary name to not be viewed as using the USAN stem. DMEPA added that the sponsor could submit such a proprietary name if they want it reviewed.

2. Discuss alternate names the Applicant submitted

Although, the Applicant has submitted alternate names Zyprexa Long Acting and Zyprexa Rezvo, they asked DMEPA for guidance on submitting additional proprietary names. DMEPA responded that they see the same challenges associated with any unconventional modifier as with Relprev. However, it is important to convey to the end-users that this product is a long-acting injection through the modifier. DMEPA asked whether the sponsor considered Depot as their modifier. The sponsor responded that they did consider Depot, but decided that they wanted a unique brand.

3. Discuss if the Applicant has conducted any studies among healthcare professionals to gather information on what is a better naming convention for the proposed Zyprexa product

DMEPA asked the Applicant if they conducted any studies to gather information on what is a better naming convention for the proposed Zyprexa product. The sponsor said that they do not have data to address this question. While the sponsor has done market research on various names, no studies have been conducted on how meaning is perceived

or interpreted. DMEPA stated that, for future submissions, these types of studies are helpful to them since they are informative during the proprietary name review process.

Action Items:

- The Applicant acknowledges that DMEPA objects to the use of the proposed proprietary name Zyprexa Relprev because it contains the USAN stem “-rev.” Therefore, the Applicant may submit an alternate spelling of the proposed modifier (e.g., Relprevv) that does not contain a USAN stem. If the sponsor plans to submit a new proprietary name for review, the sponsor needs to entitle the submission as “A Request for Proprietary Name Review,” and submit it as a separate submission to the NDA. As of October 1, 2008, all NDA and IND proprietary name reviews are subject to PDUFA IV goal dates.
- The Applicant agreed to send their proposed proprietary name via email to Daniel Brounstein, as well as make an official submission to the NDA. The Applicant plans to make a decision and send the submission by the end of the October 27th week.

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/s/

Carol Holquist
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