CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022328Orig1s000

OTHER REVIEW(S)

505(b)(2) ASSESSMENT

Application Information		
NDA # 22328	NDA Supplement #:S-	Efficacy Supplement Type SE-
Proprietary Name: Intermezzo Established/Proper Name: zolpidem tartrate SL Dosage Form: SL tablets Strengths: 1.75 mg and 3.5 mg oral SL tablets		
Applicant: Transcept Pharma, Inc.		
Date of Receipt: original submission 9/30/08; re-sub 1/14/11; re-sub 9/27/11		
PDUFA Goal Date: 11/27/11	Action Goal Date (if different): 11/23/11	
Proposed Indication(s): as needed, middle-of-the- night (MOTN) insomnia		

GENERAL INFORMATION

1. Is this application for a drug that is an "old" antibiotic as described in the Guidance to Industry, Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act? (Certain antibiotics are not entitled to Hatch-Waxman patent listing and exclusivity benefits.)

YES ☐ NO X

*If "**YES**," proceed to question #3.*

2. Is this application for a recombinant or biologically-derived product and/or protein or peptide product?

YES ☐ NO X

*If "**YES** "contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

INFORMATION PROVIDED VIA RELIANCE (LISTED DRUG OR LITERATURE)

3. List the information essential to the approval of the proposed drug that is provided by reliance on our previous finding of safety and efficacy for a listed drug or by reliance on published literature. *(If not clearly identified by the applicant, this information can usually be derived from annotated labeling.)*

Source of information (e.g., published literature, name of referenced product)	Information provided (e.g., pharmacokinetic data, or specific sections of labeling)
NDA 19908 Ambien (zolpidem tartrate)	Three Biopharm studies; specific sections PI changed
	Five clinical studies; specific sections PI changed

4. Reliance on information regarding another product (whether a previously approved product or from published literature) must be scientifically appropriate. An applicant needs to provide a scientific "bridge" to demonstrate the relationship of the referenced and proposed products. Describe how the applicant bridged the proposed product to the referenced product(s). (Example: BA/BE studies)

This NDA comprises of the following 3 single-dose pharmacokinetic (PK)/ bioequivalence (BE) bridging studies in healthy adult and elderly subjects. Study ZI-15, provides comparative bioavailability information relative to reference Ambien®. Study ZI-14 includes comparative bioavailability of Intermezzo® 1.75 mg and 3.5 mg in elderly and adult cohorts. Study ZI-13 provides a bridging link between IND formulation and final commercial formulation used in different studies. Final commercial formulation was used in most of the studies including pivotal BE, pharmacodynamic, and efficacy studies.

RELIANCE ON PUBLISHED LITERATURE

5. (a) Does the application rely on published literature to support the approval of the proposed drug product (i.e., the application *cannot* be approved without the published literature)?

YES x NO ☐

*If "**NO**," proceed to question #6.*

(b) Does any of the published literature necessary to support approval identify a specific (e.g., brand name) *listed* drug product?

Ambien (zolpidem tartrate) x NO ☐

YES

*If "**NO**", proceed to question #6*
*If "**YES**", list the listed drug(s) identified by name and answer question #5(c)*

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(c) Are the drug product(s) listed in (b) identified by the applicant as the listed drug(s)?

YES X NO ☐

RELIANCE ON LISTED DRUG(S)

Reliance on published literature which identifies a specific approved (listed) drug constitutes reliance on that listed drug. Please answer questions #6-10 accordingly.

6. Regardless of whether the applicant has explicitly referenced the listed drug(s), does the application **rely** on the finding of safety and effectiveness for one or more listed drugs (approved drugs) to support the approval of the proposed drug product (i.e., the application cannot be approved without this reliance)?

YES x NO ☐

*If "**NO**," proceed to question #11.*

7. Name of listed drug(s) relied upon, and the NDA/ANDA #(s). Please indicate if the applicant explicitly identified the product as being relied upon (see note below):

Name of Drug	NDA/ANDA #	Did applicant specify reliance on the product? (Y/N)
Ambien	19908	yes

Applicants should specify reliance on the 356h, in the cover letter, and/or with their patent certification/statement. If you believe there is reliance on a listed product that has not been explicitly identified as such by the applicant, please contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.

8. If this is a supplement, does the supplement rely upon the same listed drug(s) as the original (b)(2) application? N/A

YES ☐ NO

*If "**NO**", please contact the (b)(2) review staff in the Immediate Office, Office of New Drugs.*

9. Were any of the listed drug(s) relied upon for this application:
   a. Approved in a 505(b)(2) application?

YES NO X

*If "**YES**", please list which drug(s).*

Name of drug(s) approved in a 505(b)(2) application: none

   b. Approved by the DESI process?

YES ☐ NO x

*If "**YES**", please list which drug(s).*

Name of drug(s) approved via the DESI process:

   c. Described in a monograph?

YES ☐ NO x

*If "**YES**", please list which drug(s).*

Name of drug(s) described in a monograph:

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