

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022370Orig1s000

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO BLDG 22, Mail Stop 4447)**

DATE RECEIVED:

April 19, 2007

DESIRED COMPLETION DATE:

June 20, 2007

OSE CONSULT #:

2007-923 and 2007-924

DATE OF DOCUMENT:

April 13, 2007

TO: Bob Rappaport, MD
Director, Division of Anesthesia, Analgesia, and Rheumatology Products
HFD-170

THROUGH: Todd Bridges, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support

FROM: Kimberly Pedersen, RPh, Safety Evaluator
Division of Medication Errors and Technical Support

PRODUCT NAME:

(b) (4)
(Tramadol Hydrochloride) Extended-release Capsules
100 mg, 200 mg, and 300 mg

NDA SPONSOR:

Cipher Pharmaceuticals, Ltd.

NDA#: (b) (4)

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary names, (b) (4) and (b) (4).
2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review in order to minimize potential errors with the use of this product. Please submit revised labels and labeling for review and comment when available.
3. DDMAC finds the proprietary names (b) (4) and (b) (4) acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. Please copy DMETS on any correspondence forwarded to the sponsor with information pertaining to this review. Additionally, we would be willing to meet with the Division for further discussion if needed. If you have further questions or need clarifications, please contact Cheryl Wiseman, OSE Project Manager, at 301-796-0567.

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**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Kimberly Culley-Pedersen
9/11/2007 11:31:34 AM
DRUG SAFETY OFFICE REVIEWER

Todd Bridges
9/11/2007 02:11:40 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
9/11/2007 04:03:15 PM
DRUG SAFETY OFFICE REVIEWER
Also signing for Carol Holquist, DMETS Director