APPLICATION NUMBER:
022370Orig1s000

PROPRIETARY NAME REVIEW(S)
### Product Name

(Tramadol Hydrochloride) Extended-release Capsules

100 mg, 200 mg, and 300 mg

### NDA Sponsor

Cipher Pharmaceuticals, Ltd.

### Recommendations:

1. DMETS does not recommend the use of the proprietary names, and .

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 and 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.
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