

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
201655Orig1s000

ENVIRONMENTAL ASSESSMENT

14. ENVIRONMENTAL ASSESSMENT

**Claim for Categorical Exclusion of
Oxymorphone Hydrochloride (b) (4) Extended-Release Tablets
5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg
from the Environmental Assessment Requirements of 21 CFR 25.40**

In accordance with 21 CFR 25.31(b), Endo Pharmaceuticals Inc. claims a categorical exclusion from the environmental assessment requirements of 21 CFR 25.40 for approval of this application.

Based upon the estimate of the highest quantity of the active moiety to be produced (for direct use) in the next 5 years, the estimated concentration of the active moiety at the point of entry into the aquatic environment will be below 1 part per billion (ppb). Therefore, this action is subject to a categorical exclusion and will not require the preparation of an environmental assessment. The figures used for this calculation are available upon request.

To our knowledge, no extraordinary circumstances exist pertaining to this action.

ADEQUATE - see page 74 of 9/8/10 CMC review.