

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-071/001

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

NDA 21-071/S-001

The Human Pharmacokinetics and Bioavailability section, AND Non-Clinical Pharmacology and Toxicology section for this NDA application are available by cross-reference to the original NDA dated November 1998. No new, or updated information/data was submitted to this supplement (S-001) for these sections, and no reviews were required by these disciplines. The labeling changes made by the company are acceptable.

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ON ORIGINAL