



Food and Drug Administration
Rockville MD 20857

JAN 07 2005

Endo Pharmaceuticals
Attention: Mary Alice Raudenbush
100 Painters Drive
Chadds Ford, PA 19317

Docket No. 2004P-0149/CP1
Docket No. 2004P-0150/CP1

Dear Ms. Raudenbush:

This is to inform you that we are deferring action with respect to your petitions filed on March 26, 2004 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Acetaminophen and Oxycodone Orally Disintegrating Tablets, 325 mg/2.5 mg, 325 mg/5 mg, 325 mg/7.5 mg and 325 mg/10 mg. The listed drug product to which you refer in your petition is Percocet®, approved under ANDAs 40-330 and 40-434, held by Endo Pharmaceuticals.

Your requests involve a change in dosage form from that of the listed drug. The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new indications, new dosage forms, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. Your pending ANDA suitability petitions are affected by this Act because they are petitions for a change in dosage form. If the change proposed in an ANDA suitability petition does not qualify for a full waiver of the pediatric studies, that petition will be denied because, under PREA, clinical studies are required to demonstrate the safety and or effectiveness of the change (Section 505(j)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act).

The reason that action on your petitions is being deferred is because changes in dosage form are subject to PREA. However, we note that you have indicated that pediatric studies are ongoing for Percocet Tablets. Therefore, the FDA will defer action on these petitions until the studies are completed and submitted to the FDA for evaluation.

2004P-0149

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A copy of this letter deferring action on your petitions will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler". The signature is fluid and cursive, with a long horizontal stroke at the end.

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research