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March 13, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
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AMENDMENT TO CITIZEN PETITION 99P-5105/CP 1

On November 19, 1999, undersigned submitted a Citizen Petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. 355(j)(2)(C)), requesting the Commissioner of Food and Drugs to make a determination that two drug products described in the Petition are suitable for consideration in an abbreviated new drug application (ANDA). A copy of the filed Citizen Petition, which is incorporated by reference, is attached to this Amendment.

In the filed Petition, King & Spalding requested a determination that a drug product containing 9.25 mg oxycodone hydrochloride, 0.85 mg oxycodone terephthalate, and 650 mg acetaminophen, and a drug product containing 7.0 mg oxycodone hydrochloride, 0.57 mg oxycodone terephthalate, and 500 mg acetaminophen in a tablet for oral administration are suitable for evaluation under an ANDA.

The reference listed drug upon which this petition was based is Endo Pharmaceuticals' 4.5 mg oxycodone hydrochloride, 0.38 mg oxycodone terephthalate, and 325 mg aspirin in a tablet for oral administration. Approved Drug Products with Therapeutic Equivalence Evaluations 18th Edition ("The Orange Book"), p. 3-33 (N07337 006).

By this Amendment Petitioner withdraws the request for incrementally increasing doses of 500 mg and 650 mg of the acetaminophen component of the proposed products and requests only a change from 325 mg aspirin (in the reference product) to 325 mg acetaminophen (in the acetaminophen component of the two proposed products). The Petition remains the same for the oxycodone hydrochloride and oxycodone terephthalate component of the proposed products.

99P-5105

SUP 1

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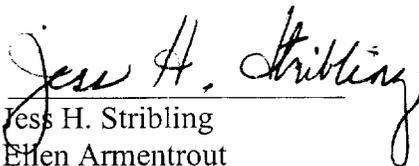
As a result of this Amendment, the total daily dose of acetaminophen will not exceed 4 grams. The maximum daily dose of oxycodone hydrochloride/oxycodone terephthalate/acetaminophen 9.25 mg/ 0.85 mg/ 325 mg is six tablets, which is 1950 mg acetaminophen/day. The maximum daily dose of oxycodone hydrochloride/oxycodone terephthalate/acetaminophen 7.0 mg/ 0.57 mg/ 325 mg is eight tablets, which is 2600 mg.

Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this Amendment, combined with the filed Petition, includes all information and views on which the Petition relies, and that it includes representative data and information known to us which are unfavorable to the Petition.

Sincerely,

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By: 
Jess H. Stribling
Ellen Armentrout

Attachments