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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20857

Citizen Petition

The undersigned submits this petition pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") and 21 C.F.R. §§ 10.30 and 314.93 to request that the Commissioner of Food and Drugs ("FDA") withdraw the approval of a particular abbreviated new drug application suitability petition ("ANDA suitability petition") that (1) is not in compliance with the Pediatric Research Equity Act of 2003 ("PREA"); and (2) does not satisfy other criteria for approval of an ANDA suitability petition.

A. Action Requested

We request that FDA withdraw approval of the ANDA suitability petition that was assigned Docket No. 93P-0346/CP1 and approved on November 15, 1994 (*see* Letter from Douglas L. Sporn, Acting Director, Office of Generic Drugs to Mikart, Inc. (November 15, 1994); Attachment 1.). We are not aware of any other, similar suitability petitions that have been approved or may be currently pending before FDA. However, if any such petitions exist for a comparable combination drug product, we request that their approval be withdrawn or denied on the same grounds.¹

¹ Petitioner is aware that a suitability petition for the combination product at issue was filed under FDA Docket No. 03P-0398 on August 18, 2003. That petition was formally withdrawn from consideration on November 21, 2003 (Attachment 2).

B. Statement of Grounds

The suitability petition filed as Docket No. 93P-0346/CP1 requested FDA authorization to submit an ANDA for tablet and capsule combination analgesic products containing 325 mg acetaminophen, 50 mg butalbital, 40 mg caffeine, and 5 mg hydrocodone bitartrate as the active ingredients. The petition was based on a change in active ingredient compared with the approved drug product Fioricet® with Codeine Capsules (325 mg acetaminophen, 50 mg butalbital, 40 mg caffeine, and 30 mg codeine phosphate). FDA advised at that time that clinical investigations were not considered necessary to establish the safety and effectiveness of the new combination product.

No ANDA for the specified combination has been approved since FDA approved the suitability petition in November 1994, nor are we aware that any such ANDA has ever been submitted for agency review.

Withdrawal of the prior suitability petition approval is warranted at this time for the following reasons:

Lack of Pediatric Waiver Determination. The Pediatric Research Equity Act of 2003 required that each person submitting, on or after April 1, 1999, a drug product application or supplemental application for a new active ingredient include certain assessments of the drug product for pediatric use, or establish that waiver or deferral of pediatric assessments is appropriate. *See generally* 21 U.S.C. § 355c(a).

FDA has interpreted the PREA to preclude the approval of pending suitability petitions, and to suspend the approval of certain previously approved petitions, unless and until FDA determines that the product would qualify for full waiver of pediatric clinical studies. *E.g.*, Letter from Gary Buehler, Director, Office of Generic Drugs to Kleinfeld, Kaplan and Becker regarding Docket No. 02P-0233/CP1 (Feb. 11, 2004) (Attachment 3). As noted, the PREA applies to new drug applications and supplemental applications -- as compared to suitability petitions -- submitted to FDA on or after April 1, 1999 (*see* PREA § 4(b)). Thus, the FDA policy reasonably applies to the suitability petition at issue.

To the petitioner's knowledge, FDA has made no determination that pediatric studies can be waived, such that ANDA submission would be conceivable pursuant to Docket No. 93P-0346/CP1.

Need for Further Clinical Investigation. Even if FDA were to determine that pediatric clinical studies are not required to allow reinstatement pursuant to PREA of the suitability petition approval under Docket No. 93P-0346/CP1, FDA must still withdraw its approval of that suitability petition because new clinical investigation is required to establish the safety and effectiveness of the product. FDA has changed its position since 1994 concerning the proposed combination drug and advised an interested party that new clinical data will be required to

establish safety and effectiveness. *See* Letter from Christina M. Markus to Division of Dockets Management regarding Docket No. 03P-0398 (Dec. 8, 2003) (Attachment 4).

FDA may not approve a suitability petition if it finds that “investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug.” 21 U.S.C. § 355(j)(2)(C); 21 C.F.R. § 314.93(e). Likewise, the agency may not maintain approval of a suitability petition when basis for denial exists. 21 C.F.R. § 314.93(f) (authorizing withdrawal of approval of a suitability petition if FDA receives information demonstrating the petition no longer satisfies conditions for approval).

C. Environmental Impact

The actions requested in this petition are subject to a categorical exclusion under 21 C.F.R. § 25.31.

D. Economic Impact

Information on the economic impact of this proposal will be submitted upon request of the Commissioner.

E. Certification

The undersigned certifies that, to her best knowledge and belief, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the petitioner that are unfavorable to the petitioner.

Respectfully submitted,



Christina M. Markus

Attachments

cc: Mr. Gary Buehler, Director
Office of Generic Drugs (w/attach.)