



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

3055 '00 APR 24 AIO:33

Mikart Inc.
Attention: Cerie B. McDonald
1750 Chattahoochee Ave. N.W.
Atlanta, GA 30318

APR 14 2000

Docket No. 99P-1657/CP1

Dear Ms. McDonald:

This is in response to your petition filed on May 28, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Acetaminophen, Butalbital, and Caffeine Tablets and Capsules, 650 mg/50 mg/40 mg. The listed drug product to which you refer in your petition is Fioricet®, (Acetaminophen, Butalbital, and Caffeine) Tablets, 325 mg/50 mg/40 mg, manufactured by Novartis.

Your request involves a change in dosage form (i.e., from tablets to capsules) and a change in strength of the Acetaminophen component (i.e., from Acetaminophen 325 mg to Acetaminophen 650 mg) from that of the listed drug product. The Agency notes that you propose both tablet and capsule forms for your proposed drug products. The changes you request are the type of changes that are authorized under the Act.

We have reviewed your petition under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that ANDAs may be submitted for the above-referenced drug products.

In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed products in the pediatric population, because these specific drug products do not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and are not likely to be used in a substantial number of pediatric patients.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a dosage form and strength which differs from the dosage form and strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form and strength.

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The Agency finds that the changes in dosage form and strength for the specific proposed drug products do not pose questions of safety or effectiveness because the uses, and route of administration of the proposed drug products are the same as that of the listed drug product. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

When ANDAs are submitted for your proposed drug products, the proposed labeling should reflect the maximum number of tablets per day that can be administered for your proposed drug products (i.e., 6 tablets). The total daily dose of the acetaminophen component should not exceed the maximum total daily dose for adults of 4000 mg established by the Agency for its safe and effective range. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988).

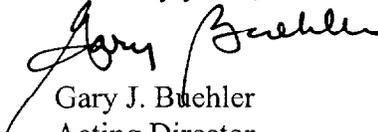
The approval of this petition to allow ANDAs to be submitted for the above-referenced drug products does not mean that the Agency has determined that the ANDAs will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the Agency.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence for this drug product prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving your petition 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,



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