DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Faulding Pharmaceutical Company
Attention: Mary Jo Guadagno
Mack-Cali Center II
650 From Road, 2nd Floor
Parasmus, NJ 07652

Docket No. 03P-0110/CP1

Dear Ms. Guadagno:

This is in response to your petition filed on March 20, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Epirubicin Hydrochloride Injection, 2 mg/mL, 5 mL vials (10 mg total drug content) and 75 mL vials (150 mg total drug content). The listed drug products to which you refer in your petition are Ellence® (Epirubicin Hydrochloride) Injection, 2 mg/mL, 25 mL vials (50 mg total drug content) and 100 mL vials (200 mg total drug content) approved under NDA 50-778 held by Pharmacia and Upjohn.

Your request involves a change in strength (total drug content) from that of the listed drug products (i.e., from 2 mg/mL, 25 mL vials [50 mg total drug content] and 100 mL vials [200 mg total drug content] to 2 mg/mL, 5 mL vials [10 mg total drug content, a new lower strength] and 75 mL vials [150 mg total drug content, an intermediate strength]). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

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

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

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

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The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA 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 FDA.

For your information, the listed drug product to which you refer is covered by a period of orphan drug exclusivity which appears in the Approved Drug Products With Therapeutic Equivalence Evaluations, 23rd Edition, published by the FDA. The existence of such exclusivity will require a statement upon submission of an ANDA for your proposed drug product and may also affect the approval date of any ANDA.

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 products 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 for these drug products to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA 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. Please note that once an application is approved for a drug product that is the same as the drug product that is the subject of this petition, then that drug product will be a listed drug. Thereafter, the petition may not be utilized as the basis for submission of an ANDA.

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