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March 19, 2003

Dockets Management Branch
Food and Drug administration
Department of Health and Human Services
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

RE: ANDA Suitability Petition
Epirubicin Hydrochloride Injection, 2 mg/mL

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR §10.20, 10.30, and 314.93 to request the Commissioner of the Food and Drug Administration to make a determination that an Abbreviated New Drug Application may be submitted for Epirubicin Hydrochloride Injection, 2 mg/mL in a strength of 10 mg/5 mL and 150 mg/75 mL.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration make a determination to permit a change in the strength (total drug content) to allow for submission of an Abbreviated New Drug Application for Epirubicin Hydrochloride Injection, 2 mg/mL , in strengths of 10 mg/5 mL and 150 mg/75 mL. The basis of the Petition is the reference listed drug, Ellence ™, marketed by the innovator Pharmacia and Upjohn. Ellence ™ is available in two strengths; a single use vial containing 50 mg/25 mL or 200 mg/100 mL of Epirubicin Hydrochloride Injection. Pharmacia and Upjohn received approval for the 50 mg/25 mL and 200 mg/100 mL vial product under NDA 50-778 on September 15, 1999.

B. Statement of Grounds

Section 505(j)(2)(C) of the Food, Drug and Cosmetic Act provides for submission of an ANDA for a new drug that differs in strength from a listed drug provided that FDA has approved a petition seeking permission to file such an application. The subject of this petition for Epirubicin Hydrochloride Injection is to permit a change in strength (total drug content) from that of the listed drug. The reference listed drug product Ellence ™ marketed by the innovator, Pharmacia and Upjohn, is available as a vial containing 50 mg/25 mL or 200 mg/100 mL. The proposed drug product will be in the same concentration, 2 mg/mL, as the reference listed drug product, but in strengths of 10mg/5 mL and 150 mg/75 mL.

03P-0110

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Product	**Dosage Form**	**Route of Administration**	**Strength**
Pharmacia and Upjohn's Ellence ™	Liquid	Intravenous	Epirubicin Hydrochloride 50 mg/25 mL and 200 mg/100 mL
Proposed Epirubicin Hydrochloride Injection	Liquid	Intravenous	Epirubicin Hydrochloride 10 mg/5 mL and 150mg/75 mL

The proposed strengths are clearly contemplated in the approved labeling of the listed drug. The proposed strengths contain the drug amount recommended in the approved labeling for dilution with 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection to make an Epirubicin Hydrochloride Infusion which is administered over a period of 3 to 5 minutes.

Epirubicin Hydrochloride Injection is currently approved in two fill sizes, 50 mg/25 mL and 200 mg/100 mL. However, the approved labeling for Epirubicin Hydrochloride Injection clearly contemplates use of starting doses of 100 mg/m^2 to 120 mg/m^2 administered by slow intravenous infusion. The proposed strengths (10 mg and 150 mg total drug content) will provide practitioners with convenient alternatives to the currently approved strength.

The proposed strengths will allow for the preparation of the approved dose of 100 mg/m^2 by using one vial of 150 mg/75 mL and two vials of 10 mg/5 mL compared to four vials of 50 mg/25 mL with considerable product being wasted.

The proposed strengths clearly conform to the dosage modifications and administration recommendations listed in the approved package insert of the reference listed drug. Since the need to open multiple vials will be reduced, the proposed drug product will minimize the potential for contamination resulting from the handling of the product, such as blood borne pathogens from cut fingers and glass particles. The proposed presentation will also provide a reduction in hazardous waste disposal and cost for the course of therapy.
The subject drug is intended for use only as described in the **Indications** and **Dosage and Administration** sections of the approved labeling. Draft labeling is provided in **Attachment I.**

Included in **Attachment II** is the package insert for Ellence ™, marketed by Pharmacia and Upjohn. The labeling for the proposed drug is essentially identical to that of Pharmacia Upjohn's Ellence ™, but differs only with respect to the description of the product, product name, dilution volume, the how-supplied statement, and the specific manufacturer's information.

The proposed strengths do not pose questions of safety or effectiveness because the uses, doses and route of administration of the proposed products are the same as those of the listed drug. The only difference between the proposed products and the approved product is strength (total drug content). The proposed doses are reflected in the approved labeling of the listed drug. For the above reasons, the undersigned requests that the Commissioner approve this petition and find that an application for Epirubicin Hydrochoride Injection, 10 mg/5 mL and 150 mg/75 mL is suitable for submission as an ANDA.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact Statement

According to 21 CFR 10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

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

Sincerely,

Mary Jo Guadagno

Mary Jo Guadagno
Regulatory Affairs Associate

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Attachment 1 – Draft labeling
Attachment 2 – Labeling for Ellence ™