March 24, 2006

Division of Dockets Management
Food and Drug Administration, HFA-305
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

0289 '06 MAR 24 P2:35

CITIZEN PETITION

AAC CONSULTING GROUP

7361 Calhoun Place,
Suite 500
Rockville, Maryland 20855-2765
301.838.3120
fax: 301.838.3182

Dear Sir or Madam:

The undersigned, on behalf of a client, submits this petition in quadruplicate pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30 requesting the Commissioner of the Food and Drug Administration to declare that the drug product Epirubicin Hydrochloride Injection, 2 mg/ml, in vials of 10 mg/5ml, 20 mg/10ml and 100 mg/50ml are suitable for submission in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration make a determination that Epirubicin Hydrochloride Injection, 2 mg/ml in vial sizes of 10 mg/5ml, 20 mg/10ml and 200 mg/100ml are suitable for submission in an ANDA. The Reference Listed Drug (RLD) upon which this petition is based is Ellence® Injection, 2mg/ml in vial sizes of 50 mg/25ml and 200 mg/100ml manufactured by Pfizer, Inc., which appears in the Electronic Orange Book **(Attachment 1)**. Therefore, the petitioner seeks the submission of Epirubicin Hydrochloride Injection, 2 mg/ml, in the vial sizes of 10 mg/5ml, 20 mg/5ml and 100 mg/ml which differ from that of the listed drug product.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in strength from a listed drug product provided the FDA has approved a petition that proposed the filing of such an application. The petitioner is maintaining the approved 2 mg/ml dosage strength for all their vial sizes. They are requesting approval for submitting three additional vial sizes of the same strength injection, namely, 10 mg/5ml, 20 mg/10ml and 100 mg/50ml. The proposed drug product in the aforementioned three additional vial sizes represents the same uses, dosage form, and route of administration of those approved for the listed drug product.

2006P-0131 CP1

There should be no question of safety or efficacy raised regarding the requested new vial sizes of Epirubicin Hydrochloride Injection, 2 mg/ml as the strength, uses, dose, and route of administration are the same as that of the listed drug product. The approved labeling of the listed drug product is included as **Attachment 2.** Labeling of the proposed product **(Attachment 3)** will be the same as the approved labeling of the reference listed drug product with the exception to the introduction of the aforementioned three additional vial sizes in the "Description" and "How Supplied" section.

C. Economic Impact

Pursuant to 21 CFR 10.30 (b), economic impact information is to be submitted only when requested by the Commissioner. Information will be submitted, if requested.

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 is unfavorable to the petition.

Respectively submitted,

Salvatore J. Pinella

Salvatore J. Pinella
Senior Consultant