DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4591 7 AUG 23 P2:06

AUG 22 2007

Lachman Consultant Services, Inc.
Attention: Joan Janulis
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 2006P-0145/CP1

Dear Ms. Janulis:

This is in response to your petition filed on March 31, 2006 requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Gemcitabine for Injection USP, 2 g/vial. The listed drug product to which you refer in your petition is Gemzar® (gemcitabine) for Injection, 1 g/vial, held by Eli Lilly and Company. The petitioner also references the 200 mg/vial strength of gemcitabine.

Your request involves a change in strength (total drug content) from that of the listed drug product (i.e., from 1 g/vial to 2 g/vial). 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 product.

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 product does not pose questions of safety or effectiveness because the uses, dosage form, and route of administration of the proposed drug product are the same as that of the listed drug product. The FDA 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.

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

2006P-0145 PAV 1

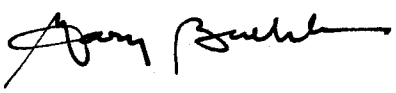
For your information, the listed drug product to which you refer is covered by patent and exclusivity that appears in the Approved Drug Products With Therapeutic Equivalence Evaluations, 27th Edition, published by the FDA. The existence of such patent protection and exclusivity will require patent certifications and exclusivity statements 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 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 for the drug product 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 same drug product 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 product that is the same as the subject of an approved petition, that drug product will be the listed drug. Thereafter, a 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