



AUG 31 2004 --

Lachman Consultant Services, Inc.  
Attention: Robert W. Pollock  
1600 Stewart Avenue  
Westbury, NY 11590

Docket No. 2003P-0091/CP1

Dear Mr. Pollock:

This is in response to your petition filed on March 10, 2003, and your amendment dated January 9, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) and waiver of pediatric safety and effectiveness assessment requirements for the following drug products: Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-release Capsules, 10 mg/8 mg and 5 mg/4 mg. The listed drug product to which you refer in your petition is Tussionex® (Hydrocodone Polistirex and Chlorpheniramine Polistirex) Extended-release Suspension, 10 mg/8 mg, approved under NDA 19-111, held by Celltech Pharmaceuticals, Inc. We also refer to the comments dated June 12, 2003, submitted by Celltech Pharmaceuticals, Inc. and your reply to those comments dated August 1, 2003.

Your request involves a change in dosage form from that of the listed drug product (i.e., from an extended-release suspension to extended-release capsules). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition and the related documents 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 change in dosage form that differs from the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage forms.

The FDA finds that the change in dosage form for the specific proposed drug products does 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 product. 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 product.

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Lachman Consultant Services, Inc.  
Hydrocodone Polystyrene and Chlorpheniramine Polystyrene Extended-Release Capsules  
10mg/8mg and 5mg/4mg

The approval of your suitability 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.

This letter also represents the FDA determination that a partial waiver of pediatric assessment requirements may be granted for the above-referenced drug products, to waive these requirements in pediatric patients younger than six years of age.

Section 505B of the Act, requires that applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations, unless the requirement is waived or deferred.

The FDA has determined that your proposed change in dosage form is subject to pediatric assessment requirements, but has concluded that: (1) assessments are not required to demonstrate the safety and effectiveness of your proposed products in pediatric patients six years of age and older because the specific drug products are adequately labeled for this population; and (2) assessments can be waived with respect to pediatric patients younger than six years of age because, for this population, the change in dosage form does not represent a meaningful therapeutic benefit over existing therapies and is not likely to be used in a substantial number of patients. For your information, the listed drug product to which you refer is covered by a period of patent protection which appears in the Approved Drug Products With Therapeutic Equivalence Evaluations (Orange Book) published by the FDA. The existence of such a patent will require a certification upon submission of an ANDA for your proposed drug products 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 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 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.

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Lachman Consultant Services, Inc.

Hydrocodone Polistirex and Chlorpheniramine Polystirex Extended-Release Capsules

10mg/8mg and 5mg/4mg

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,

A handwritten signature in black ink, appearing to read "Gary Buehler", with a long horizontal flourish extending to the right.

Gary J. Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research