

ENCLOSURE C



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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JUL 05 2005

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

Docket No. 2004P-0353/CP1

Dear Mr. Pollock:

This is in response to your petition filed on August 5, 2004, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Famotidine Orally-Dissolving Strips, 10 mg. The reference listed drug to which you refer in your petition is Pepcid AC® (Famotidine) Chewable Tablets, 10 mg, approved under NDA 20-801 held by Merck.

Your request involves a change in dosage form from that of the listed drug product (i.e., from chewable tablets to orally-dissolving strips). 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.

In addition, this petition and your waiver request were evaluated with respect to the "Pediatric Research Equity Act of 2003" (PREA). PREA requires that all 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. Your pending ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form. The product is labeled for over-the-counter use in adults and children 12 years and over. Famotidine use in patients younger than 12 years of age would require a physician's intervention for proper diagnosis and treatment, and for accurate dosing based upon the child's weight. It is more appropriate to use the prescription product famotidine for oral suspension, which is adequately labeled for pediatric use. Therefore, the FDA has determined that your proposed change in dosage form is subject to PREA, but has concluded that the requirements for PREA have already been met.

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 form.

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The FDA finds that the change in dosage form for the specific proposed drug product does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug product are the same as that of the listed drug product. The FDA concludes, therefore, that clinical investigations are not necessary to show safety or effectiveness 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.

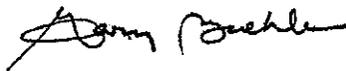
The approval of this petition to allow an ANDA to be submitted for the above-referenced drug product does not mean that the FDA has determined that an ANDA will be approved for the drug product. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed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

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 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

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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August 4, 2004

OVERNIGHT COURIER 8/04/04

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

CITIZEN PETITION

The undersigned 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 on behalf of a client requesting the Commissioner of Food and Drug to declare that the drug product, Famotidine Orally Dissolving Strips 10 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner declare that Famotidine Orally Dissolving Strips 10 mg is suitable for submission as an ANDA. The reference-listed drug (RLD) product upon which this petition is based is Pepcid AC® Chewable Tablets (famotidine) 10 mg. Pepcid AC® Chewable Tablets 10 mg is approved under NDA 20-801 and is manufactured by Merck. The RLD product is approved for marketing as an over-the-counter (OTC) drug product. A copy of the appropriate page (Page 4-5) from the *Approved Drug Products with Therapeutic Equivalence Evaluations* 24th edition that lists the approval is provided in Attachment 1. The petitioner seeks a change in the dosage form, from a chewable tablet to an orally dissolving strip, from that of the RLD product.

B. Statement of Grounds

The RLD product, Pepcid AC® Chewable Tablets, is currently available in a 10 mg chewable tablet dosage form and is approved for marketing OTC. The proposed drug product is consistent with the currently approved RLD product's labeling with the exception of the dosage form and directions for administration (because the proposed product is an orally dissolving strip). Although we are not aware of any FDA approved drug products presently marketed in an orally dissolving strip dosage form, there are a number of products that are marketed over-the-counter that utilize this dissolving film technology. For instance, a number of breath freshener products are marketed using this technology. The dosage form will contain inactive ingredients that are generally recognized as safe (GRAS) for use in food or have been used in previously approved drug products. The orally dissolving strip is designed to be placed on the tongue and will dissolve within a few seconds after contact. In that regard, this dosage form is directly analogous to the multitude of fast-dissolving and disintegrating tablets that have been approved

by the Agency. Each dosage unit (strip) will contain 10 mg of famotidine and the sponsor will, in its application, provide information demonstrating that its proposed product is bioequivalent to the RLD product, Pepcid AC® Chewable Tablets, 10 mg.

The proposed product will provide an alternate dosage form that may prove to be more convenient for patients who have difficulty swallowing a tablet or who do not like to chew tablets. Pepcid AC® Chewable Tablets 10 mg is marketed as an OTC product for the prevention and relief of heartburn. The proposed product will be labeled in accordance with the approved labeling of the RLD product upon which this petition is based. Any difference in the labeling will relate solely to the difference in dosage form and the method of administration (dissolving the strip on the tongue as opposed to chewing and swallowing the tablet) and those differences that may be necessary because the products are made by different manufacturers or because of patent or exclusivity protections.

Copies of the labeling of the RLD product upon which this petition is based and draft labeling for the proposed product are included in Attachments 2 and 3, respectively. The proposed labeling is the same as the approved RLD product labeling, including doses recommended, indications and conditions of use, with the exceptions identified above.

The petitioner requests that the Commissioner find that a change in dosage form from a chewable tablet to an orally dissolving strip raises no questions of safety or effectiveness.

C. Pediatric Waiver Request

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 that amended the Federal Food, Drug, and Cosmetic Act to provide the Agency authority to require drug firms to study drugs in pediatric patients, if the Agency concludes that such study would provide beneficial health data for that patient population. The Act specifically requires that a request for a new dosage form is subject to a pediatric evaluation. The act also provides for a waiver from such requirement if the drug:

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit an ANDA filing.

The RLD product is currently available in a conventional immediate-release chewable tablet for OTC use and is not, according to the approved labeling, recommended for use in pediatric patients below 12 years of age. While heartburn may be seen in pediatric patients less than 12 years of age, a physician's intervention would be appropriate, since heartburn in this age group is predominantly associated with GERD, a condition appropriately treated with prescription medication. Famotidine was on the FDA list of drug products for which studies may provide health benefits to the pediatric population. The NDA holder received a written request for pediatric studies, conducted those studies, and received a 6-month period of pediatric exclusivity associated with those studies. FDA's list of written requests issued to companies for

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pediatric studies indicates that Merck received a written request for the conduct of pediatric studies on Famotidine issued by the Agency on December 20, 1999¹. The studies were conducted and submitted to the Agency on August 28, 2000, and as noted in FDA's review of this submission, "the sponsor has satisfied the requirements of the Written Request for Pediatric Studies and pediatric exclusivity has been granted."² Based on the submission of these studies and consistent with the rules governing pediatric exclusivity, the 6-month pediatric exclusivity extension for existing patents or exclusivity was applied to all of the firm's products containing famotidine. In that regard, because the requirements for the conduct of pediatric studies were satisfied by those studies submitted by the innovator in response to the written request, there should be no need to repeat such studies or engage in additional studies for the product proposed by this petition seeking the same condition of use as that of the RLD product upon which this petition is based. The change in dosage form to an orally dissolving strip from an immediate-release chewable tablet provides a product with similar form and function to that of the RLD product (i.e., a dosage form that does not require administration with water to prevent or relieve heartburn). The proposed change in dosage form does not represent a meaningful therapeutic benefit over existing therapies and would likely be used only for those patients for whom treatment is currently indicated in the labeling.

D. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

E. Economic Impact

The petitioner believes that this is not applicable in this case, but agrees to provide such an analysis, if requested by the Agency.

F. 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 includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Robert W. Pollock, Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

RWP/pk

¹ FDA Summary of Approval of NDA 20-958 Medical Review, Part 1 http://www.fda.gov/cder/foi/nda/2000/20-958_Pepcld.htm accessed 5/30/04

² *ib. id.*

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Attachments:

1. *Approved Drug Products with Therapeutic Equivalence Evaluations* 24th Edition, page 4-5
2. Pepcid AC® Chewable Tablets approved labeling
3. Draft labeling for the proposed famotidine orally dissolving strip, subject of this petition

cc: Emily Thakur (Office of Generic Drugs)

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