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

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

March 16, 2006

OVERNIGHT COURIER 3/16/06

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

Dear Sir or Madam:

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 the Food and Drug Administration to declare that the drug products, Cetirizine Hydrochloride Orally Disintegrating Tablets, 5 mg and 10 mg, are suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Cetirizine Hydrochloride Orally Disintegrating Tablets, 5 mg and 10 mg, are suitable for submission in an ANDA. The Reference-Listed Drug (RLD), upon which this petition is based, is Zyrtec® (cetirizine hydrochloride) Tablets, 10 mg. In addition, the petitioner also refers to the approved, 5 mg strength of Zyrtec® (cetirizine hydrochloride) Tablets listed in Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) in support of this petition. The petitioner thus seeks a change in dosage form (from a conventional, immediate-release tablet to an orally disintegrating tablet) from that of the listed drug products.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The listed drug, Zyrtec® Tablets by Pfizer, is a conventional, immediate-release tablet for oral administration containing cetirizine hydrochloride, 5 mg and 10 mg. Zyrtec® Tablets is the subject of NDA 19-835, which was approved on December 8, 1995. A copy of the listing from the Electronic Orange Book, accessed on (March 16, 2006) is included in Attachment A.[1] The proposed drug products are orally disintegrating tablets that represent the same strengths as the listed drugs (namely the 10 mg RLD and the approved 5 mg product) referred to in this petition, but in a different dosage form.

2006P-0122 CP1

The orally disintegrating tablet form is designed to facilitate the ease of administration for patients who cannot swallow or have difficulty swallowing conventional tablets. Additionally, the proposed product represents a convenient alternative to Zyrtec® Oral Syrup and Zyrtec® Chewable, which are also marketed by Pfizer[2]. The proposed product is designed to dissolve rapidly on the tongue, and be swallowed with or without water. Thus, the proposed product will provide a convenient alternative to the already available dosage forms of cetirizine hydrochloride.

Copies of the approved labeling for the listed drug upon which this petition relies, and draft labeling for the proposed product are included in Attachments B and C, respectively.[3] Please note that the draft labeling for the proposed product will be revised to include the inactive ingredients and a complete "How Supplied" section when the ANDA is submitted. The proposed labeling is the same as the approved labeling for the listed drug with the exception of changes that are necessary because the manufacturer of the generic product differs from that of the listed drug, and those changes that are commensurate with the change in dosage form proposed in this petition, i.e., the ability of the tablet to dissolve on the tongue. (A listing of differences between the labeling for the proposed product and the approved labeling for Zyrtec® is appended as Attachment D.) There are no other differences between the conditions of use prescribed, recommended or suggested in the labeling for the proposed, orally disintegrating tablet and those approved for the listed drug. Please be advised that the ANDA applicant will demonstrate that the proposed orally disintegrating tablet is bioequivalent to the RLD.

Applicability of Pediatric Research Equity Act

The Pediatric Research Equity Act (PREA), which was signed into law on December 2, 2003, requires that all applications for approval of a new active ingredient, indication, dosage form, dosing regimen or route of administration contain a pediatric assessment unless the applicant has obtained a waiver or deferral under Section 505(B)(b). If the pediatric assessment requires the conduct of clinical studies, the application will be ineligible for submission as an ANDA.

The petitioner hereby requests that a waiver of the requirement to conduct pediatric studies be granted in respect to the proposed product that is the subject of this petition. The following supports the petitioner's request for a waiver:

1. On May 15, 1998, Pfizer obtained approval of Supplement #S-005 for NDA 19-835, which comprised a revision of the package insert labeling to provide for the use of Zyrtec® to treat seasonal and perennial allergic rhinitis and chronic idiopathic urticaria in pediatric patients, ages 2-5 years.
2. On October 21, 2002, Pfizer obtained approval of Supplements #S-008 and #S-015 for NDA 19-835, which comprised a revision to the package insert to provide for the use of Zyrtec® for (1) treatment of perennial allergic rhinitis in adults and children 6 months and older and (2) treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months and older.[4]
3. Points 1 and 2 above demonstrate that the labeling for the listed drug, Zyrtec® contains information in respect to the use of cetirizine hydrochloride in pediatric patients for the range of indications for which the drug is approved.
4. The petitioner, by way of an ANDA submitted pursuant to this petition (once approved), will seek approval for the same conditions of use as given in the approved labeling for

the listed drug. Thus, the proposed product will not represent any meaningful therapeutic benefit over the presently available dosage forms of cetirizine hydrochloride.

Thus, because the requirements for the conduct of pediatric studies were satisfied by Pfizer, and because the approved labeling for the listed drug on which the labeling for the petitioner's product will be based already contains comprehensive information regarding the use of the drug in pediatric patients, there should be no need to repeat or conduct additional studies for the proposed product for which this petition is being submitted.

For the reasons cited above, the petitioner requests that the Commissioner find that a change in dosage form from a conventional, immediate-release tablet to an orally disintegrating tablet containing cetirizine hydrochloride, 5 mg and 10 mg, raises no questions of safety or effectiveness. The petitioner requests that the Commissioner approve the petition accordingly.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner believes that analysis of economic impact does not apply to the submission of this petition, but agrees to provide such an analysis if requested by the Agency.

E. Certification

The undersigned certifies, that to the best of his/her knowledge and, 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.

Respectfully Submitted,

Jean Janulis, Director
Lachman Consultant Services, Inc.

JJ/pk

---

[1] The list was accessed on (March 16, 2006) from the following web address: http://www.fda.gov/cder/pediatric/wrlist.htm

[2] Zyrtec is also available in an oral syrup containing 5 mg cetirizine hydrochloride / mL and in chewable tablets containing 5 mg or 10 mg of cetirizine hydrochloride.

[3] Pfizer uses a combined package insert for its conventional tablet, chewable tablet and oral syrup forms of Zyrtec®. Please note that this petition does not rely on the chewable tablet and/or oral syrup form of the product.

[4] Pursuant to Pfizer's conduct of pediatric studies and the approval of these NDA supplements, a six-month period of pediatric exclusivity attached to the unexpired, Orange Book-listed patent that claims the RLD, Zyrtec® Tablets. Additionally, Pfizer received a three-year period of marketing exclusivity in respect to the labeling for the new patient population covered under these NDA supplements.

Attachments:

A. Copy of Search Results from the Electronic Orange Book (accessed on March 16, 2006), documenting the listed drug status of Zyrtec® (cetirizine hydrochloride) Tablets, 5 mg and 10 mg

B. Copy of Approved Labeling for the Listed Drug (Zyrtec®)

C. Draft Labeling for the Proposed Product

D. Listing of Labeling Differences

cc: Arianne Camphire (OGD)

B05JD6075

From: Origin ID: (516)683-1881
Westbury Office
LACHMAN CONSULTANT SERVICES
1600 STEWART AVE
SUITE 604
WESTBURY, NY 11590

FedEx Express

CLS022306/16/19

Ship Date: 16MAR06
ActWgt: 1 LB
System#: 1879030/INET2400
Account#: S *********

REF: LCS Documents

Delivery Address Bar Code

SHIP TO: (301)827-6860 **BILL SENDER**

Division of Dockets Management
Food & Drug Administration
DHHS, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

STANDARD OVERNIGHT

FRI
Deliver By:
17MAR06

TRK# 7920 4504 0320

FORM 0201

IAD A2

20852 -MD-US
DSR

ZM GAIA

Shipping Label: Your shipment is complete

1. Use the 'Print' feature from your browser to send this page to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $500, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.