



May 12, 2006

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:

This Citizen's Petition is submitted by Strides Inc., under the authority of 21 CFR §10.30, 21 CFR §314.93, and Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FDCA). The petitioner is requesting that the Food and Drug Administration permit the filing of an Abbreviated New Drug Application for a proposed drug product that has the same active ingredient, is of the same strength, and is expected to have the same therapeutic effect as that of a reference product in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, but differs in dosage form.

#### A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration is being requested to declare that:

- (1) A new drug application for Cetirizine Hydrochloride Soft Gelatin Capsules 5mg and 10mg is suitable for submission as an Abbreviated New Drug Application (ANDA), pursuant to 21 CFR §314.94;
- (2) The reference product on which the contents of this petition are based is Zyrtec® (Cetirizine Hydrochloride Tablets 5mg and 10mg);
- (3) Therefore, a request is being made to change the dosage form from tablet to soft gelatin capsule.

At this time, the undersigned is also requesting a waiver of the requirement to conduct pediatric studies in accordance with 21 CFR §314.55(c)(2). The basis for this request is discussed in Section C below.

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## **B. Statement of Grounds**

Section 505(j)(2)(C) of the FDCA allows for the submission of an Abbreviated New Drug Application for a proposed new drug product that differs in dosage form from that of the Reference Listed Drug on which it is based, provided that the Commissioner of Food and Drugs has approved a petition, filed by or on behalf of the applicant, requesting a declaration that an application to market a drug product with such change is suitable for an ANDA submission.

The Commissioner of Food and Drugs has previously approved ANDA suitability petitions of this nature, in particular, those in which the petitioners have sought to change the dosage form in order to make an alternate dosage form available for those who have difficulty swallowing tablets or simply prefer the alternative.

In support of this petition, the following information is being provided:

- (1) The proposed drug product is a soft gelatin capsule with the same active ingredient, the same strength, and the same route of administration as that of the reference product, Zyrtec® (Cetirizine Hydrochloride) available as 5mg and 10mg tablets. A copy of the most recent Orange Book listing of "Approved Drug Products with Therapeutic Equivalence Evaluations" is provided (Attachment 1).
- (2) The proposed drug product will be labeled with the same conditions of use as the reference product, and is expected to have the same therapeutic effect when used as indicated in the labeling. Labeling for the proposed drug product and the reference product will differ with respect to the manufacturer identification and contact information, and the inactive ingredients. A draft of the proposed drug product labeling is provided (Attachment 2). A copy of the current reference product labeling also is provided (Attachment 3).

## **C. Pediatric Waiver Request**

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 (the PREA) that amended the FDCA 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 pediatric evaluation.



We assert the change in dosage form for the 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.

In addition, the petitioner notes that the reference product is approved for use in adults and children 2 years of age and older for seasonal allergic rhinitis and adults and children 6 months of age and older for seasonal allergic rhinitis and chronic urticaria. The approved labeling states: "The safety of ZYRTEC has been demonstrated in pediatric patients aged 6 months to 11 years. The safety of ZYRTEC, at daily doses of 5 or 10 mg, has been demonstrated in 376 pediatric patients aged 6 to 11 years in placebo-controlled trials lasting up to four weeks and in 254 patients in a non-placebo-controlled 12-week trial. The safety of cetirizine has been demonstrated in 168 patients aged 2 to 5 years in placebo-controlled trials of up to 4 weeks duration. On a mg/kg basis, most of the 168 patients received between 0.2 and 0.4 mg/kg of cetirizine HCl. The safety of cetirizine in 399 patients aged 12 to 24 months has been demonstrated in a placebo-controlled 18-month trial, in which the average dose was 0.25 mg/kg bid, corresponding to a range of 4 to 11 mg/day. The safety of ZYRTEC syrup has been demonstrated in 42 patients aged 6 to 11 months in a placebo-controlled 7-day trial. The prescribed dose was 0.25 mg/kg bid, which corresponded to a mean of 4.5 mg/day, with a range of 3.4 to 6.2 mg/day.." 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 reference product upon which this petition is based.

Finally, we assert the drug is not likely to be used in a substantial number of pediatric patients because Zyrtec® already is available as a fruit-flavored syrup, which is a more convenient and preferred dosage form for children. As noted above in Section B. Statement of Grounds, the primary therapeutic benefit to be gained from the approval of Cetirizine Hydrochloride Soft Gelatin Capsules is to make an alternate dosage form available for those who have difficulty swallowing tablets. Given that Zyrtec® already is available as a fruit-flavored syrup, which is a more convenient and preferred dosage form for children, this therapeutic benefit does not extend to 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.

#### **D. Environmental Impact**

The applicant claims a categorical exclusion under 21 CFR §25.31.

#### **E. Economic Impact**

Information will be provided upon request of the Commissioner.

# Strides

## 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 that it includes representative data and information known to be unfavorable to the petition.

Respectfully submitted by:



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Enclosures: Attachments 1, 2 and 3