



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 Loratadine Soft Gelatin Capsules 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 Claritin® (Loratadine Tablets 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, Claritin® (Loratadine) available as 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 PREA specifically requires that a request for a new dosage form is subject to pediatric evaluation. The PREA also provides for a waiver from such requirement if the drug:

1. Does not represent a meaningful therapeutic benefit over existing therapies; and
2. 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.

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 drug is not likely to be used in a substantial number of pediatric patients because Claritin® 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 Loratadine Soft Gelatin Capsules is to make an alternate dosage form available for those who have difficulty swallowing tablets. Given that Claritin® 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.

Finally, "Approximately 300 pediatric patients 6 to 12 years of age received 10 mg loratadine once daily in controlled clinical trials for a period of 8 to 15 days. Among these, 188 children were treated with 10 mg loratadine syrup once daily in placebo-controlled trials. Adverse events in these pediatric patients were observed to occur with type and frequency similar to those seen in the adult population. The rate of premature discontinuance due to adverse events among pediatric patients receiving loratadine 10 mg daily was less than 1%. Sixty pediatric patients 2 to 5 years of age received 5 mg loratadine once daily in a double-blind, placebo-controlled clinical trial for a period of 14 days. No unexpected adverse events were seen given the known safety profile of loratadine and likely adverse reactions for this patient population. The following adverse events occurred with a frequency of 2 to 3 percent in the loratadine syrup-treated patients (2 to 5 years old) during the placebo-controlled trial, and more frequently than in the placebo group: diarrhea, epistaxis, pharyngitis, influenza-like symptoms, fatigue, stomatitis, tooth disorder, earache, viral infection, and rash."¹ 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.

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.



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:

A handwritten signature in black ink that reads "N. Gaddipati".

Nehru Gaddipati, PhD, RPh
President, R&D

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Enclosures: Attachments 1, 2 and 3

¹ http://www.rxlist.com/cgi/generic/lorat_ad.htm