DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

2512 10 FEB -2 P5:28 FEB 01 2010

Strides Inc.
Attention: Nehru Gaddipati, Ph.D., RPh
37-41 Veronica Avenue
Somerset, New Jersey 08873

Docket No. FDA-2006-P-0087
Legacy Docket No. 2006P-0208

Dear Dr. Gaddipati:

This is in response to your petition filed on May 15, 2006, requesting permission to file an Abbreviated New Drug Application (ANDA) for Loratadine Capsules (soft gelatin), 10 mg. The listed drug to which you refer in your petition is Claritin (Loratadine) Tablets, 10 mg, NDA 019658 held by Schering Plough.

Your request involves a change in dosage form. We have reviewed your petition and have determined that it is now moot. On June 16, 2008, Schering Plough was approved for Loratadine Capsules, 10 mg, NDA 021952. Because this product is approved and is designated as the reference listed drug for Loratadine Capsules, there is no need for a decision with respect to your petition on the identical product. You may submit an ANDA using NDA 021952 as the basis of submission.

A copy of this letter will be placed on public display in the Division of Dockets Management, 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

FDA-2006-P-0087

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