DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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FEB 01 2010

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

Docket No. FDA-2006-P-0286
Legacy Docket No. 2006P-0207

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 Cetirizine Hydrochloride Capsules (soft gelatin), 5 mg and 10 mg. The listed drug to which you refer in your petition is Zyrtec (Cetirizine Hydrochloride) Tablets, 5 mg and 10 mg, NDA 019835 held by McNeil Consumer.

Your request involves a change in dosage form. We have reviewed your petition and have determined that it is now moot. On July 23, 2009, Banner Pharmacaps' NDA 022429 was approved. NDA 022429 is for Cetirizine Hydrochloride Capsules, 5 mg and 10 mg. Because this product is approved and is designated as the reference listed drug for cetirizine hydrochloride capsules, there is no need for a decision with respect to your petition on the identical product. You may submit an ANDA using NDA 022429 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-0286

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