ANDA 212795

ANDA APPROVAL

Strides Pharma Inc.
U.S. Agent for Tenshi Kaizen Private Limited
2 Tower Center Boulevard, Suite 1102
East Brunswick, NJ 08816
Attention: Chandran Tiruvattar
Senior Director, Regulatory Affairs

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on August 21, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Loratadine Orally Disintegrating Tablets USP, 5 mg (OTC).

Reference is also made to the complete response letter issued by this office on June 19, 2020, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act and is safe and effective for over-the-counter (OTC) use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. We have determined your Loratadine Orally Disintegrating Tablets USP, 5 mg (OTC) to be bioequivalent to the reference listed drug, Claritin RediTabs Orally Disintegrating Tablets, 5 mg, of Bayer HealthCare LLC.

Further reference is made to FDA's Competitive Generic Therapy Designation – Grant letter dated December 28, 2018.

We note that Tenshi Kaizen Private Limited (Tenshi) was granted a CGT designation for Loratadine Orally Disintegrating Tablets USP, 5 mg (OTC). Tenshi is the "first approved applicant" for such competitive generic therapy, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Tenshi is eligible for 180 days of CGT exclusivity for Loratadine Orally Disintegrating Tablets USP, 5 mg (OTC), under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity will begin to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Tenshi, as specified in section 505(j)(5)(B)(v) of the FD&C Act. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C Act, this 180-day CGT exclusivity will not block approval of other applications until Tenshi has commenced commercial marketing. Please submit a correspondence to this ANDA informing the

Agency of the date you begin commercial marketing. Please also submit notice of first commercial marketing via e-mail to the Patent and Exclusivity Team at CDER - OGDPET@fda.hhs.gov. This email should be sent the same day you commence commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 505(j)(5)(D)(iv) of the FD&C Act. Please be aware that, pursuant to this forfeiture rule, you will forfeit your eligibility for the 180-day CGT exclusivity period for Loratadine Orally Disintegrating Tablets USP, 5 mg (OTC), if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[1] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the *Federal Register* notice announcing facility fee amounts.

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at https://www.fda.gov/media/71211/download.
The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Catherine Poole

Digitally signed by Catherine Poole
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