DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

Mylan Institutional LLC
Attention: Martina O'Sullivan
Senior Director, Regulatory Affairs
4901 Hiawatha Drive
Rockford, IL 61103

8/26/2014

Strides Inc. (A Mylan Company)
U.S. Agent for: Agila Specialties Private Limited
Attention: Anil Sachdeva, Senior Director, Regulatory Affairs
201 South Main Street
Suite #3
Lambertville, NJ 08530

Dear Sir or Madam:

This letter is being sent under Section 506C(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for the reasons set forth below.

Section 506C of the FD&C Act requires a manufacturer of a drug product that is "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition" to notify the Food and Drug Administration (FDA or the Agency) of: (1) a permanent discontinuance in the manufacture of the drug; or (2) an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption[1] in the supply of that drug in the United States; and (3) the reason(s) for such discontinuance or interruption of manufacturing (FD&C Act § 506C(a)). The notification must be submitted at least 6 months prior to the date of the discontinuance or interruption of manufacturing, or as soon as practicable (FD&C Act § 506C(b)). Compliance with this notification requirement is essential to facilitating the mitigation and/or prevention of a shortage or potential shortage, and ultimately may ensure availability of critical drugs for patients.

If a person fails to submit this required notification within the required timeframe, FDA must issue a letter to that person informing the person of the failure to comply with the FD&C Act (FD&C Act § 506C(f)).

Haloperidol lactate injection is a product that is "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition." This product has approved indications for use in the treatment of schizophrenia.

FDA was notified on November 8, 2013 by Strides, Inc. of the transfer of ownership of Pfizer, Inc.'s ANDA 078347 for haloperidol lactate injection 5 mg/mL to Agila Specialties Private Limited. The Agency was further notified by Pfizer on December 6, 2013 that Mylan Inc. had completed the acquisition of the Agila injectable drug business from Strides Arcolab Limited, and that Pfizer had transferred the assets of products manufactured by Strides to Mylan. Haloperidol lactate 5mg/mL vials (NDC# 0069-0113-02)was listed in that December 6, 2013 communication as one of the products acquired by Mylan.

It is our understanding that sometime between December 2013 and May 2014, there was an interruption in the manufacture of this haloperidol lactate injection product that was likely to lead to a meaningful disruption in the supply of this drug product in the United States.

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1 The statute defines "meaningful disruption" to mean "a change in production that is reasonably likely to lead to a reduction in the supply of a drug by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for the product," and "does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time." Section 506C(h)(3).

The Agency learned of a significant decrease in the supply of haloperidol lactate injection from outside stakeholders in May 2014, and haloperidol lactate injection was determined to be in shortage soon thereafter, on May 27, 2014.

Our records indicate that you failed to notify the FDA of the interruption in manufacturing of this product that led to the shortage. Accordingly, we are issuing you this letter to notify you of your noncompliance with the FD&C Act.

No later than thirty calendar days after the issuance of this letter, you must submit to the Agency a written response setting forth the basis for noncompliance with Section 506C and providing the required notification, including the reason(s) for the interruption in manufacturing that led to a disruption in the supply of your haloperidol lactate injection product.

No later than forty-five calendar days after the issuance of this letter, FDA will make this letter and your response to the letter available to the public on FDA's Drug Shortage website, unless the Agency determines that this letter was issued in error, or, after review of your response, determines that there was a reasonable basis for noncompliance. In posting the letter and your response on the Drug Shortage website, FDA would protect confidential commercial information and trade secrets, if any, as required by applicable law.

If you have further questions, please contact the Drug Shortage Staff at (301) 796-1300.

Please submit all communications regarding this drug product to the following address:

Drug Shortage Staff
Food and Drug Administration
WO 22, Room 6204
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

CAPT Valerie Jensen
Associate Director
Drug Shortage Staff
Center for Drug Evaluation and Research