Prestige Brands Holdings 6/1/17

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Silver Spring, MD 20993-0002

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

June 1, 2017

WL # 594 -595

Mary Beth Fritz
Prestige Brands Holdings, Inc.
660 White Plains Road
Tarrytown, NY, 10591 USA

Mary Beth Fritz;

The United States Food and Drug Administration (FDA) has reviewed your firm's listing information provided forPediaCare Children's Plus Multi-Symptom Cold, NDC 52183-385 and PediaCare Children's Plus Flu, NDC 52183-365. Our review revealed that the listings for these products include inaccurate information. Prompt action must be taken to correct these deficiencies.

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) outlines the requirements for registration and listing of drug products. The listings for PediaCare Children's Plus Multi-Symptom Cold, NDC 52183-385, and PediaCare Children's Plus Flu, NDC 52183-365, must include "The name and quantity of each active pharmaceutical ingredient in the listed drug".[1]

A review of the listings for the products PediaCare Children's Plus Multi-Symptom Cold, NDC 52183-385, and PediaCare Children's Plus Flu, NDC 52183-365, reveals that while the active ingredient, Phenylephrine Hydrochloride appears on the copy of the label provided with the listing for each product, it is missing from the listing information in Structured Product Labeling (SPL) submitted for both drug listing files.

Your firm failed to fulfill its listing obligations under Section 510(j) of the FD&C Act, [21 U.S.C. 360(j)], which is a prohibited act under Section 301(p) of the FD&C Act, [21 U.S.C. 331(p)]. In addition, your firm's failure to fulfill its listing obligations misbrands the product under Section 502(o) of the FD&C Act [21 U.S.C. 352(o)].Introduction or delivery for introduction into interstate commerce of a misbranded product is a prohibited act under Section 301(a) [21 U.S.C. 331(a)].

Information from your firm's registration and product listings are accessible not only to FDA, but to other interested parties, including consumers. Your products' listing data has been removed from the FDA's online NDC Directory and will not be available for public viewing until the corrections are made. This is an effort to maintain a correct and accurate database in order to protect and promote the public health.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations. Your response should include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete these corrective actions within fifteen working days, state the reason for the delay and the date by which you will have completed the corrections. Please be aware that in order for your revised SPL submission to be accepted, a manual override may be required for certain types of errors. If you receive a validation error, or have any questions regarding the contents of this letter, please contact us at **edrls@fda.hhs.gov (mailto:edrls@fda.hhs.gov)** for further assistance. Include the case identification number of 594 -595 on all correspondences.

Your reply should be sent to:

Tasneem Hussain, Pharm. D.
eDRLS Staff
Food and Drug Administration
Mail Stop HFD-300
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Building 51 Room 2261

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations found in your firm's registration and product listings. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Paul Loebach

Cc: New York District Office

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[1] See FD&C Act Section 510 (j)(1)(A), 21 CFR Part 207.49 (a) (4)

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