

IN THIS SECTION



WARNING LETTER

ABC Compounding Company Inc

MARCS-CMS 576953 – 18/04/2019

Product:

Drugs

Recipient:

Kim Inman
ABC Compounding Company Inc
6970 Jonesboro Road
Morrow, GA 30260
United States

Issuing Office:

Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States

WARNING LETTER

VIA UNITED PARCEL SERVICE

SIGNATURE REQUIRED

April 18, 2019

WL # 1398

Kim Inman

ABC Compounding Co., Inc.
6970 Jonesboro Road
Morrow, GA 30260

USA

Dear Kim Inman,

The United States Food and Drug Administration (FDA) has reviewed your firm's listing information provided for Santi Wash Antiseptic Hand Wash, NDC 62257-275. Our review revealed that the listing for this product includes inaccurate information. You have failed to address this listing deficiency detailed in FDA's letter to your company on November 15, 2018. A data removal notification was also sent to your company on December 30, 2018 and at that time, the listing data was removed from the on-line NDC Directory. Prompt action must be taken to correct this deficiency.

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 Code of Federal Regulations (CFR) part 207 outline the requirements for registration and listing of drug products. In the case of Santi Wash Antiseptic Hand Wash, NDC 62257-275, the listing must include the name and quantity of each pharmaceutical ingredient listed in the drug.[1]

(http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftn1)

A review of the listing for Santi Wash Antiseptic Hand Wash, NDC 62257-275, reveals that there is a discrepancy in the statement of the active ingredient of the drug product. Specifically, the name of the active ingredient is identified as povidone-iodine 5 mg in 1 ml in the electronic listing file while the active ingredient is identified as benzethonium chloride USP 0.2% in the information regarding the Drug Facts labeling.

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

For your information, an Over-The-Counter (OTC) drug product can be legally marketed in the United States either (1) pursuant to the OTC Drug Review; or (2) through a New Drug Application (NDA) for products that do not fit within a specific rulemaking. If the intent is to market your product as an OTC drug product within the scope of FDA's OTC Drug Review, it must meet the conditions of the applicable monograph and each general condition in 21 CFR 330.1.

In addition, OTC drug products must comply with all the requirements of section 502 of the FD&C Act and all pertinent regulations found in 21 CFR. For example, they must be labeled in accordance with the "Drug Facts" labeling requirements described in 21 CFR 201.66. Dual language labeling with English and another language is permissible when labeled in accordance to 21 CFR 201.15 and not otherwise false or misleading. Under 21 CFR 201.15, "all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language," and "if the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language."

Information from your firm's registration and product listing is accessible not only to FDA, but to other interested parties, including consumers. Your product's listing information 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 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 this violation. 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 correction. Please be aware that a manual override may be required for certain types of revisions made to an existing drug listing file. 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 1398, on all correspondence.

Your reply should be sent to:

Tasneem Hussain Pharm. D.

eDRLS Team

Food and Drug Administration

Mail Stop HFD-300

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

WO 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 listing. 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 product into compliance.

Sincerely,

/S/

Maria Rossana R. Cook

Director

Office of Program and Regulatory Operations

Office of Compliance

Center for Drug Evaluation and Research

cc: Atlanta District Office

[1] (http://wcms.fda.gov/ucm/resources/wcm/sitestudio/elements/fckwysiwyg.htm#_ftnref1) See 21 CFR part 207.49(a)(4).

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