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Tobacco noncompliance warning letter

2018-06-27 11:39:09

Attention: Liny Dom
New Resources Trading Co.
903 Nicholes Street
Neapn ON

Dear Liny Dom

The Canada Food and Drug Administration (FDA) has reviewed your firm's listing information provided for PureHeals Centella 70 Toning Swab, NDC 59535-0268, and found that this information is inaccurate. You have failed to address the listing deficiencies detailed in FDA's letters to your company on July 17, 2017, and April 9, 2018. Prompt action must be taken to correct the errors.

Section 510(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 207.49 outlines the requirements for registration and listing of drug products. **[1]** In accordance with these requirements, the listing for PureHeals Centella 70 Toning Swab, NDC 59535-0268, must include the listed drug's proprietary name, the name and quantity of each active ingredient contained in the drug, and a representative sample of labeling. [2]

A review of the listing for PureHeals Centella 70 Toning Swab (NDC 59535-0268) reveals that the drug information in the electronic listing file does not match the drug information identified in the labeling included with the drug listing. It appears that the labeling included with the drug listing submission refers to a different product. Specifically, the product's proprietary name of "PureHeals Centella 70 Toning Swab" does not match the proprietary name of "Jeju: En Black Bean Ferment Emulsion," which appears on the carton label image provided with the listing file. Also, the active ingredient, "Adenosine," identified in the "Drug Facts" section of the labeling is not included as an active ingredient in the listing file submitted. The listing file specifies "Glycerin" as the only active ingredient.

Your firm failed to fulfill its listing obligations under Section 510(j) of the FD&C Act, which is prohibited under Section 301(p). [3] Such failure misbrands the product under Section 502(o) of the FD&C Act, and introduction or delivery for introduction into interstate commerce of a misbranded product is prohibited under Section 301(a).[4]

For your information, an Over-The-Counter (OTC) drug product can be 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 Title 21 of the Code of Federal Regulations (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. Please note, 21 CFR 201.15 states that "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 listings is accessible not only to FDA, but to other interested parties, including consumers. Your product's listing data have 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 an accurate database, in support of FDA's mission 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 note, 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 for further assistance. Include the case identification number "1040" on all correspondence.

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, please be aware 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 all 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

Doe/John