WARNING LETTER

Greenbrier International, Inc dba Dollar Tree

MARCS-CMS 574706 — NOVEMBER 06, 2019

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Gary M. Philbin

President and Chief Executive Officer

Greenbrier International, Inc dba Dollar Tree

500 Volvo Parkway

Chesapeake, VA 23320

United States

Issuing Office:

Center for Drug Evaluation and Research

United States

November 6, 2019

Warning Letter 320-20-07

Dear Mr. Philbin:

The U.S. Food and Drug Administration (FDA) inspected your corporate headquarters, Greenbrier International, Inc. (Greenbrier) (FEl 3005269673) at 500 Volvo Parkway, Chesapeake, Virginia, from January 14 to 18, 2019 after FDA inspections revealed violative conditions at multiple foreign drug manufacturers that supplied drugs to your distribution network. Firms inspected by FDA included contract manufacturers used to manufacture Dollar Tree's Assured Brand drugs. The FDA inspections of these foreign facilities revealed significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals, Title 21 , Code of Federal Regulations, Parts 210 and 211 (21 CFR Parts 210 and 211). Additionally, FDA inspected your distribution center warehouse located at 1330 Executive Boulevard (FEI

3004319430). Chesapeake, Virginia, from January 14 to 17, 2019. This facility operates under the name Dollar Tree Distribution. Inc. and stores your finished drug products, which it then distributes to Dollar Tree and other retail stores.

The inspection revealed that you had limited manufacturing operations at your corporate headquarters. However, the CGMP violations identified at your suppliers caused drug products manufactured by these firms to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Your receipt in interstate commerce of adulterated drugs, and the delivery or proffered delivery thereof, is a violation of section 301 (c) of the FD&C Act, 21 U.S.C. 331 (c).

We reviewed your February 5, 2019 response in detail and acknowledge receipt of subsequent correspondence.

Receipt of Adulterated Drugs from Contract Manufacturers and Suppliers

Our inspection and review of import data revealed the following:

1. Import records reviewed indicated that your firm received Acne Treatment Pads and **(b)(4)** from Shanghai Weierya Daily Chemicals Factory, FEl 3010166363, on October 9, 2017 and November 3, 2017, respectively. An inspection of Shanghai Weierya Daily Chemicals in April of 2017 revealed significant CGMP violations, including the failure to conduct component identity testing (21 CFR 211.84(d)(1)) and the failure to test each batch of drug for objectionable microorganisms prior to distribution (21 CFR 211.165(b)). As a result of these and other violations, Shanghai Weierya Daily Chemicals was placed on lmport Alert 66-40 on September 14, 2017 and issued a warning letter on February 7, 2018. FDA copied your Chief Operating Officer (COO) on the outgoing warning letter.

2. lmport records reviewed indicated that your firm received various **(b)(4)** and **(b)(4)** drug products from Hangzhou Zhongbo Industrial Company, Ltd., FEI 3008229416, from October through December of 2018. An inspection of Hangzhou Zhongbo Industrial Company, Ltd. in April of 2018 revealed significant CGMP violations, including the failure to test each batch of drug for conformance with specifications prior to release (21 CFR 211.165(a)). As a result of this and other violations, Hangzhou Zhongbo lndustiial Company, Ltd. was placed on Import Alert 66-40 on September 28, 2018 and was issued a warning letter on November 27, 2018. FDA copied your COO on the outgoing warning letter.

We note that during the inspection of your corporate headquarters, you stated that if you were made aware that a warning letter was issued to one of your suppliers or contract manufacturers, you would not purchase over-the-counter (OTC) drug products from that contract manufacturer any longer. Additionally, in your February 5, 2019 response you state, "If a drug product is placed on Import Alert 66-40 (appearing not to comply with drug manufacturing cGMPs), Greenbrier ceases importing drug products from that establishment." The import data detailed above demonstrate this is not always the case.

We also note that Greenbrier has, at various points in time, used contract manufacturers and suppliers with histories of significant drug CGMP violations. For example, our inspections revealed that beyond the facilities detailed above, your firm has used the following contract manufacturers and suppliers:

1. **(b)(4)**, FEI **(b)(4)**, which was issued a warning letter on **(b)(4)**, for, among other things, not testing raw materials prior to use in drug manufacturing and not testing finished drug products prior to distribution.

2. Bicooya Cosmetics Limited, FEI 3010671652, which was issued a warning letter on August 11, 2017. This firm was also placed on Import Alert 66-40 on June 29, 2017, for, among other things, not testing finished drug products prior to distribution and for rodent feces found throughout the manufacturing facility. FDA copied your COO on the warning letter.

3. **(b)(4)** , FEI **(b)(4)**, which was issued a warning letter on **(b)(4)**. This firm was also placed on Import Alert 66-40 on **(b)(4)** for, among other things, falsifying test results and releasing sub-potent drugs to the U.S. market. FDA copied your COO on the warning letter.

4. Ningbo Pulisi Daily Chemical Products Company, FEI 3003727322, which was issued a warning letter on August 13, 2019. This firm was also placed on Import Alert 66-40 on June 10, 2019, for, among other things, not testing raw materials for identity prior to use in drug manufacturing, and not testing finished drug products prior to release. FDA copied your COO on the warning letter.

For manufacturers that are listed on Import Alert 66-40 for failure to conform to current good manufacturing practices within the meaning of Section 501(a)(2)(B), FDA has evidence that the drugs noted in the Import Alert appear to be adulterated. You are responsible for ensuring that the drugs you distribute are manufactured in compliance with all relevant CGMP requirements for drugs. Up to elate information regarding import alerts can be found at the following FDA website: https://www.accessdata.fda.gov/cms_ia/ialist.html (https://www.accessdata.fda.gov/cms_ia/ialist.html).

Considering that FDA has found a pattern of drug manufacturers with serious CGMP violations in your supply chain, in response to this letter, provide a detailed plan to ensure you do not receive or deliver adulterated drugs in interstate commerce, in violation of section 301 (c) of the FD&C Act, 21 U.S.C. 331(c). Items in your plan should include a full evaluation of your supplier and contract manufacturer evaluation program, including a plan to audit your suppliers. Furthermore, you should also include a full reconciliation of any drugs from the manufacturers listed above, as well as for all firms or drugs currently on FDA import alerts, to determine if you have any remaining drugs in your possession, either in your distribution network or in retail stores under the Dollar Tree, Family Dollar, or any other retail store brands in your network. FDA encourages entities that engage in manufacturing related solely to drug distribution (e.g., distributors, brokers, private label distributors, own label distributors) to follow recommendations in FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements* at https://www.fda.gov/media/86193/download (https://www.fda.gov/media/86193/download).

Use of Bureau Veritas To Conduct Testing of Drug Products

You have a contractional relationship with Bureau Veritas (BVS) to conduct testing of articles (including drugs) that you distribute. FDA inspections of the aforementioned contract manufacturers and suppliers revealed that you directed your contract manufacturers and suppliers to use BVS as a contract laboratory. FDA also collected a copy of your quality manual at an FDA inspection of a BVS laboratory that indicates you require your contract manufacturers and suppliers to use BVS to test drugs distributed by Greenbrier International/Dollar Tree.

During FDA inspections of your suppliers, some of the firms listed above asserted to FDA that they relied on technical lab reports bearing both Greenbrier International and BVS logos to support release and distribution of drug products to the United States. FDA inspected one BVS location in February 2018 that generated such a technical report and found multiple inadequacies related to test methods BVS employed for the analyses of

drugs. Both during this FDA inspection, and in subsequent written correspondence submitted to the FDA, BVS representatives asserted that BVS's test methods were not suitable for drug CGMP purposes and that its test results were not suitable to make release decisions of drug products for distribution into the U.S. supply chain.

Your purchasing agreements require suppliers to use BVS testing for the purpose of acceptance of distributed drugs, despite the fact that BVS could not provide adequate assertion of drug quality. This testing cannot be used as a substitute for testing required under FDA regulations. You are responsible for ensuring that the drugs you distribute are not adulterated, including ensuring that all drug manufacturers supplying Greenbrier with drugs have had release testing conducted in accordance with CGMP requirements.

Regulatory Meeting

Upon submission of your response to this letter, please contact Ginneh Stowe, by e-mail at Ginneh.Stowe@fda.hhs.gov, to schedule a meeting to discuss the adequacy of the corrective actions you proposed to prevent the continued introduction of adulterated goods into interstate commerce.

Conclusion

Violations in this letter are not intended as an all-inclusive list. You are responsible for promptly correcting and addressing the above violations and other violations of the FD&C Act and implementing regulations. Failure to promptly correct the violations may result in legal action without further notice including, without limitation, seizure and injunction.

In addition, we note that some of the products that you import are also regulated as cosmetics. For example, you import products from Bicooya Cosmetics Limited that are both OTC drugs and cosmetics. Under section 601(c) of the FD&C Act (21 U.S.C. 361 (c)), a cosmetic shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. Some of the sanitation conditions that cause OTC drug products to be adulterated may also cause cosmetic products to be adulterated. Under section 301(a) of the FD&C Act (21 U.S.C. 331 (a)), it is a prohibited act to introduce or deliver for introduction into interstate commerce a cosmetic product that is adulterated. Additionally, the receipt in interstate commerce of adulterated cosmetics, and the delivery or proffered delivery thereof, is a prohibited act under section 301(c) of the FD&C Act.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov (mailto:CDER-OC-OMQ-Communications@fda.hhs.gov) or mail your reply to:

Kevin Maguire
Compliance Officer
U.S. Food and Drug Administration
White Oak Building 51, Room 4359
10903 New Hampshire Avenue
Silver Spring, MD 20993

Please identify your response with FEI 3005269673.

Sincerely,

/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

/S/

Alonza Cruse
Director
Office of Pharmaceutical Quality Operations
Office of Medical Products and Tobacco Operations
Office of Regulatory Affairs

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