IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. KEYSTONE LABORATORIES, INC., a corporation, MELINDA MENKE and ELIZABETH JUMET, individuals, Defendants.	Civil No: 18-2656_____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. Keystone Laboratories, Inc. ("Keystone") manufactures and sells over-the-counter drugs to consumers through third party retail outlets and directly through the company's website. Marketed as hair care and skincare products, these drugs, as required by statute and regulation, should be manufactured, processed, packaged, or held subject to current good manufacturing practice ("CGMP") for drugs. Inspections of Keystone's facilities and products have revealed numerous failures to comply with CGMP as well as failures to properly label its products. Keystone, Melinda Menke (its owner and chairperson), and Elizabeth Jumet (Keystone's president) have repeatedly failed to correct deficiencies identified in inspections by the Food and Drug Administration ("FDA").

STATUTORY FRAMEWORK

2. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Keystone, Melinda Menke ("Menke") and Elizabeth Jumet ("Jumet"), individuals (collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce:

i. drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice for drugs as set forth at 21 C.F.R. Parts 210 and 211 (hereinafter, "drug CGMP requirements"); and

ii. drugs that are misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), or (o); and

B. 21 U.S.C. § 331(k) by:

i. causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

ii. causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), or (o).

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter and all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

4. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

5. Defendant Keystone Laboratories, Inc., a Tennessee corporation, does business at 1103 Kansas Street, Memphis, Tennessee ("the Facility"), within the jurisdiction of this Court.

6. Keystone manufactures, processes, packs, labels, holds, and distributes a variety of hair and skincare products at or from the Facility, including but not limited to over-the-counter ("OTC") drugs. Such products include, but are not limited to, medicated Better Braids Spray, medicated Better Braids Un-braid, medicated Better Braids Shampoo, medicated Better Braids Leave-In-Conditioner (hereafter, "medicated Better Braids products"), Ultra Glow Fade Cream with Complexion Bar, Ultra Glow Fade Cream Oily Skin, Ultra Glow Fade Cream Normal Skin, and Ultra Glow Skin Tone Cream (hereafter, "Ultra Glow skin lightening products").

7. Defendant Melinda Menke is Keystone's owner and chairperson. Defendant Menke is responsible for all of Keystone's operations, including approving the firm's manufacturing schedules, and she exercises direct control over the firm's finances, including approving invoices. She has corresponded with FDA regarding CGMP compliance at the Facility. Defendant Menke does business within the jurisdiction of this Court.

8. Defendant Elizabeth Jumet is Keystone's President. She oversees the company's day-to-day operations, including manufacturing, regulatory affairs, marketing, sales, and human resources. Defendant Jumet performs her duties at the Facility, within the jurisdiction of this Court.

9. Defendants distribute their products through retailers across the United States. They also operate a website, keystone-labs.com, through which they sell their products directly to customers.

DEFENDANTS' VIOLATIONS OF THE ACT

Adulterated Drugs

10. A product is a drug within the meaning of the Act, inter alia, if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man," 21 U.S.C. § 321(g)(1)(C).

11. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

12. Some of Defendants' products are drugs within the meaning of the Act because, based on the intended uses stated in Defendants' labels and labeling, such products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and/or intended to affect the structure or any function of the body of man. Specifically, Defendants' medicated Better Braids products are drugs because they are intended to control dandruff and/or itching through the "medicated" action of salicylic acid. Defendants' Ultra Glow skin lightening products are drugs because they are intended to, inter alia, lighten skin by suppressing the ability of skin cells to produce pigment.

13. The Act requires manufacturers of drug products to manufacture their products in compliance with CGMP requirements for drugs, 21 U.S.C. § 351(a)(2)(B), to ensure that drugs

meet the requirements of the Act as to safety and have the identity and strength and meet the quality and purity characteristics that they purport to or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with CGMP requirements are deemed adulterated as a matter of law, without any showing of actual defect. The CGMP regulations, set forth at 21 C.F.R. Parts 210 and 211, establish the minimum CGMP requirements applicable to drugs and require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured, to prevent the production of unsafe and ineffective products.

14. FDA's inspections of the Facility have established that the methods, facilities, and controls that Defendants use for manufacturing, processing, and testing their drugs do not conform to drug CGMP requirements, and therefore, Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

15. Specifically, during FDA's most recent inspection of the Facility, dated October 30 through November 16, 2017 ("November 2017 inspection"), FDA investigators documented numerous deviations from drug CGMP requirements including, but not limited to, the following:

A. Defendants failed to ensure an appropriate laboratory determination of satisfactory conformance to final specifications of drug products prior to release, as required by 21 C.F.R. § 211.165(a), and to follow written procedures designed to prevent objectionable microorganisms in drug products, as required by 21 C.F.R. § 211.113(a). Specifically, the quality unit approved lots of Better Braids Leave in Conditioner and Better Braids Shampoo for release to the warehouse for distribution without first conducting microbiological testing. Furthermore, finished product testing was performed on a single sample, which is not representative of the batch, and inappropriately taken from the top of the bulk finished product

tank. Defendants failed to perform any analytical testing on topical finished drug products prior to release.

B. Defendants failed to establish scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b), and failed to establish and document the accuracy, sensitivity, specificity, and reproducibility of test methods, as required by 21 C.F.R. § 211.165(e). Defendants have not validated the microbial testing methods used for: 1) finished OTC topical drug products release and stability testing, and 2) purified water testing for the detection of mold or objectionable microorganisms, including *Staphylococcus aureus* (*S. aureus*).

C. Defendants failed to have and to follow an adequate written testing program with reliable, meaningful, and specific test methods designed to assess the stability characteristics of Defendants' drug products, as required by 21 C.F.R. § 211.166(a)(3). For example, Defendants failed to validate their test methods to demonstrate that such methods are both stability-indicating, that is, able to detect the changes with time of the chemical, physical, or microbiological properties of their drug products, and specific so that the contents of active ingredients, degradation products, impurities, and other components of interest can be accurately measured without interference. Defendants also failed to test drug products for impurities and degradants.

D. Defendants failed to have written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a). Specifically, Defendants failed to validate their 1) drug manufacturing processes to ensure consistent drug

product quality, 2) purified water system to assure that it maintains its chemical and microbiological attributes (there are no maintenance records or cleaning procedures for this system), and 3) equipment cleaning processes to ensure that contamination from previously manufactured products does not contaminate new products.

E. Defendants failed to review and approve written procedures for the microbial testing method used for finished drug products, as required by 21 C.F.R. § 211.100(a). Specifically, Defendants' quality control unit failed to approve the current microbial testing data forms for antimicrobial effectiveness testing.

17. During FDA's inspection immediately preceding the November 2017 inspection, dated February 1 through 5, 2016 ("February 2016 inspection"), FDA investigators documented numerous deviations from drug CGMP requirements including, but not limited to, the following:

A. Defendants failed to thoroughly investigate the failure of a batch to meet its specifications, extend the investigation to other batches of the same drug product and other drug products that may have been associated with the specific failure, and document the investigation, as required by 21 C.F.R. § 211.192. Specifically, according to Defendants' finished product testing, a lot of medicated Better Braids Spray and a lot of medicated Better Braids Un-braid tested positive for *S. aureus*. The quality unit disqualified these positive test results without sound scientific justification and evidence, and approved the products for release to the warehouse for distribution without documentation of further investigation. Defendants then distributed both products to customers.

Staphylococcus species, especially *S. aureus*, are microorganisms that can cause diseases, including skin infections, bacterial conjunctivitis, and life-threatening infections if they enter the blood stream or invade deeper parts of the body. Skin and hair products that are

contaminated with S. aureus pose a risk of infection for users who have breaches in skin integrity, such as open cuts, or if the products make contact with the users' eyes.

B. Defendants failed to ensure an appropriate laboratory determination of satisfactory conformance to final specifications of drug products prior to release, as required by 21 C.F.R. § 211.165(a), and to follow written procedures designed to prevent objectionable microorganisms in drug products, as required by 21 C.F.R. § 211.113(a). Specifically, the quality unit approved a lot of medicated Better Braids Un-Braid for release to the warehouse for distribution on the same day that microbiological testing of this lot began. That is, the quality unit released this lot on the same day that the test sample from the lot was collected. The test sample should have been incubated for 72 hours before the test result could be read to determine conformance with microbiological specifications, as required by Defendants' microbiology standard operating procedure ("SOP").

C. Defendants failed to ensure that laboratory records include complete data derived from all tests necessary to assure compliance with established specifications and standards, as required by 21 C.F.R. § 211.194(a). Specifically, the quality unit approved medicated Better Braids Shampoo and Ultra Glow Fade Cream with Complexion Bar for release to the warehouse for distribution without data from microbiological testing to support such approval and release. Defendants' records noted only that microbiological testing had been completed but did not include any data derived from such testing to assure compliance with microbiological specifications.

D. Defendants failed to have and to follow an adequate written testing program with reliable, meaningful, and specific test methods designed to assess the stability characteristics of Defendants' drug products, as required by 21 C.F.R. § 211.166(a)(3).

Specifically, the Defendants failed to conduct stability testing at the time points specified in their stability SOP for 17 out of the 18 lots of products that FDA investigators reviewed including, but not limited to, Ultra Glow Fade Cream with Complexion Bar.

18. In addition, records that FDA investigators collected from the Facility during the February 2016 inspection and/or records submitted by Defendants to FDA after the inspection showed Defendants':

A. Failure to keep an adequate written record of each complaint that includes the findings of any investigation and follow-up, as required by 21 C.F.R. § 211.198(b)(2). Specifically, Defendants received customer complaints of, among other things, break-outs with red bumps, facial burning, and skin rash in connection with Ultra Glow Fade Cream with Complexion Bar. Defendants' investigation forms for these complaints were blank and Defendants did not otherwise document the findings of any investigation or follow-up.

B. Failure to have laboratory controls that include scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity, in violation of 21 C.F.R. § 211.160(b). Specifically, during the June 6 to 10, 2011, inspection of the Facility, FDA investigators documented that, in assessing the stability of Ultra Glow Skin Tone Cream, Defendants relied on a pH range, 2.5 to 6.0, that was more permissive than the finished product pH specification, 5.0 to 6.0. Defendants did not document any scientific justification for the finished product pH specification. During the February 2016 inspection, FDA investigators collected stability records showing that this product had failed its specifications for appearance, color, and odor before its two-year expiration date. Hydroquinone-containing products with low pH, ranging from 2.5 to 4.9, can cause irritation, and users with open cuts can experience increased absorption that result in more

severe adverse reactions. Despite the stability failures and customer complaints of Ultra Glow Skin Tone Cream turning brown and causing skin rash, irritation, and facial burning, records that Defendants submitted to FDA after the February 2016 inspection show that Defendants continued to rely on the stability pH range of 2.5 to 6.0 for this product without adequate scientific justification.

19. Many of the drug CGMP deviations that FDA investigators observed during the November 2017 and February 2016 inspections are the same as, or similar to, deviations observed during FDA's previous inspections of the Facility, including the inspections between March 9 and 13, 2015, September 8 and 12, 2014, August 12 and 15, 2013, August 15 to 29, 2012, and/or June 6 to 10, 2011. Such CGMP deviations included, but were not limited to, Defendants' failure to: ensure that testing and release of drug products for distribution include appropriate laboratory determination of satisfactory conformance to final specifications prior to release, as required by 21 C.F.R. § 211.165(a); ensure that the responsibilities and procedures applicable to the quality control unit are fully followed, as required by 21 C.F.R § 211.22(d); ensure that stability test methods are stability-indicating and test for product impurities and degradants, as required by 21 C.F.R. § 211.166(a)(3); conduct stability testing, as required by 21 C.F.R. § 211.166(a)(3); ensure that the water system that Defendants use for manufacturing drugs is protected from microbial contaminants, as required by 21 C.F.R. § 211.100; and/or adequately investigate customer complaints, as required by 21 C.F.R. § 211.192.

20. FDA's inspections of the Facility establish that Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for their manufacture, processing, packing, or holding do not conform to and are not operated or administered in conformity with drug CGMP requirements.

21. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

22. Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of drugs while they are held for sale after shipment of one or more of their components in interstate commerce.

Misbranded Drugs

23. A drug is deemed to be misbranded if it fails to display required labeling information "prominently" and in "such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." See 21 U.S.C. § 352(c).

24. OTC drugs are subject to the labeling requirements set forth in 21 C.F.R. Part 201, and in any applicable OTC monograph regulations. Defendants' medicated Better Braid products are OTC drug products subject to the Final Monograph for Miscellaneous External Drug Products for Over-the-Counter Human Use: Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products, 21 C.F.R. Part 358, Subpart H. Accordingly, the medicated Better Braid products must conform to 21 C.F.R. Part 201 and Part 358, Subpart H. FDA reviewed the labeling for Defendants' medicated Better Braid products in November 2017 and determined that those products fail to conform to 21 C.F.R. Part 201 and Part 358, Subpart H and are therefore misbranded within the meaning of 21 U.S.C. § 352(c). For example:

A. Medicated Better Braids Leave-in Conditioner, medicated Better Braids Spray, and medicated Better Braids Un-Braid fail to include an accurate statement of the general pharmacological categories or principal intended actions of these drugs, i.e., "dandruff [insert

product form]" or "anti-dandruff [insert product form]," on their principal display panels ("PDPs"), in violation of 21 C.F.R. §§ 201.61(b) and 358.750(a)(1).

B. Medicated Better Braids Spray, medicated Better Braids Un-Braid, medicated Better Braids Shampoo, and medicated Better Braids Leave-in Conditioner fail to include on their labels the required information in both English and French, as required by 21 C.F.R. § 201.15(c)(2) and (3). In particular, the labels of these products include representations in English and French but certain Drug Facts information required by or under the authority of the Act (e.g., "Drug Facts" required under 21 C.F.R. § 201.66(c)(1), "Active ingredient" required under § 201.66(c)(2), and "Purpose" required under § 201.66(c)(3)) appears only in English.

C. Medicated Better Braids Spray, medicated Better Braids Un-Braid, and medicated Better Braids Leave-in Conditioner fail to include the language "Apply to affected areas one to four times daily or as directed by a doctor" under their directions for use, as required by 21 C.F.R. § 358.750(d)(2).

D. Medicated Better Braids Shampoo fails to include the language "For best results use at least twice a week or as directed by a doctor" under its directions for use, as required by 21 C.F.R. § 358.750(d)(1).

25. A drug is deemed to be misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use." Adequate directions for use means directions under which a layman can use a drug safely and for the purposes for which it is intended, and they include frequency and duration of administration. See 21 C.F.R. § 201.5. Under 21 C.F.R. § 358.750(d)(1), products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated as a shampoo, require directions that state, "For best results use at least twice a week or as directed by a doctor." Under 21 C.F.R.

§ 358.750(d)(2), products containing active ingredients for the control of dandruff, seborrheic dermatitis, or psoriasis when formulated as a cream, ointment, lotion, or hair grooms, require directions that state, "Apply to affected areas one to four times daily or as directed by a doctor." Defendants' medicated Better Braids Shampoo and medicated Better Braids Leave in Conditioner are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they are nonprescription drugs that do not include such adequate directions for use in their labeling.

26. A drug is deemed to be misbranded within the meaning of the Act, 21 U.S.C. § 352(o), if it was manufactured in an establishment not duly registered under 21 U.S.C. § 360, or if it was not included in a list a manufacturer is required to file with FDA under 21 U.S.C. § 360(j). Defendants have registered the Facility with FDA. They have not, however, filed a list of all of the drugs that they manufacture at the Facility for commercial distribution, as required by 21 U.S.C. § 360(j). Specifically, Defendants have failed to meet their section 360(j) listing obligation for the following drugs: Ultra Glow Fade Cream with Complexion Bar 3.6 oz. and Ultra Glow Fade Cream with Aloe Vera Oily Skin 2 oz. See 21 C.F.R. §§ 207.41 and 207.49. Accordingly, these drug products are misbranded within the meaning of 21 U.S.C. § 352(o).

27. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), and/or (o), as set forth above.

28. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become misbranded, within the meaning of 21 U.S.C. § 352(c), (f)(1), and/or (o), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Interstate Commerce

29. Defendants ship their products in interstate commerce. For example, Defendants ship medicated Better Braids Leave-in Conditioner from Tennessee to Georgia.

30. Defendants receive raw materials at the Facility from outside Tennessee, which they use to manufacture their drug products. For example, Defendants received at the Facility raw material, salicylic acid, from Illinois for use in manufacturing medicated Better Braids Spray.

HISTORY

31. Defendants are well aware that their violations of the Act could lead to regulatory action.

32. In addition to FDA's seven inspections of the Facility between 2017 and 2011, as described in Paragraphs 15, 16, and 18, FDA also inspected the Facility on several prior occasions, including in 2006, 2005, 1999, and 1993. At the close of each of these inspections, FDA investigators provided an FDA List of Inspectional Observations ("Form FDA-483") to Keystone's management and discussed the observations with them.

33. In addition, FDA held a regulatory meeting with Keystone's General Manager/Comptroller and Quality/Innovations Manager on January 31, 2014. During this meeting, FDA discussed violations at the Facility and reiterated that continuing violations could result in a seizure or an injunction.

34. FDA also issued Defendant Menke, as Owner/Chairman of Keystone, two Warning Letters, dated March 18, 2013, and September 13, 1993, respectively. The March 18, 2013, Warning Letter discussed, among other things, Defendants' drug CGMP deviations and misbranding violations. The September 13, 1993, Warning Letter discussed Defendants' CGMP

deviations. Both Warning Letters notified Defendants that failure to promptly correct violations may result in further action, including an injunction.

35. FDA also issued an Untitled Letter dated December 3, 1999, to Defendant Menke, discussing CGMP deviations observed during FDA's inspection of the Facility between September 28 and October 4, 1999, and encouraging her to take corrective actions.

36. Defendants have routinely promised to make corrections. Nevertheless, their violations persist.

37. Accordingly, unless restrained by this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a) and (k).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with drug CGMP requirements and the Act, in a manner that has been found acceptable by FDA; and

B. Defendants revise their product labels and labeling, list all of their drugs with FDA, and otherwise ensure that all of their drugs, to FDA's satisfaction, comply with the Act, including but not limited to, 21 U.S.C. § 352(c), (f)(1), and (o), and applicable regulations.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), or (o); and

B. violating 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), or (o).

III. Order that FDA be authorized to inspect Defendants' facilities and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

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IV. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 25th day of September, 2018.

Respectfully submitted,

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