U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Transdermal Cap Inc. 8/10/15

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
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August 10, 2015

WARNING LETTER
CIN-15-475751-23

VIA UPS

Michael I. Rabin, MD
CEO
Transdermal Cap Inc.
3615 Superior Avenue
Building 42, Suite 4203D
Cleveland, OH 44114

Dear Dr. Rabin:

During an inspection of your firm, located in Cleveland, OH on June 11 through 30, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer of the LaserCap™, which promotes hair growth. Under section 201(h) of the

Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response, dated July 17, 2015, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (FDA 483) that was issued to you. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). Specifically, your "Complaint Handling" procedure, QMS-211 Rev A, dated 06/01/2013 has not been implemented, in that:

a) From 11/9/2014-5/25/2015, a total of 125 complaints were received and documented informally in emails and on a spreadsheet. Complaint form, #211.2.A, which is required to be completed per your Complaint Handling procedure, was not completed for each of these complaints.

b) You failed to document the following information for these 125 complaints:

- The date the complaint was closed to assure that complaints were processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1).

- The evaluation of these complaints to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting, as required by 21 CFR 820.198(a)(3). Three complaints received involved patient reactions (scalp "burning", hair "shedding", and head "itches").

- The review and evaluation of all complaints to determine whether an investigation is necessary. If no investigation is made, the reason why and the name of the individual responsible for the decision not to investigate, as required by 21 CFR 820.198(b).

- The investigation of any complaint involving the failure of the device, labeling, or packaging to meet any of its specifications, as required by 21 CFR 820.198 (c).

Your corrective actions appear to be appropriate; however, a follow-up inspection will be necessary to evaluate the implementation and effectiveness of the actions.

2. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). Specifically, your "Corrective and Preventive Action" procedure, QMS-212 Rev A, dated 06/01/2013 has not been adequately implemented in that:

a) Data sources are not being analyzed to identify existing and potential causes of nonconforming product or other quality problems, as required by 21 CFR 820.100(a)(1).

b) The corrective action of changing the design of the wire configuration and the connection to the housing that was taken as a result of complaints of the LaserCap's low voltage (battery) wire fraying was not documented.

c) The verification, validation and effectiveness, and approval of the corrective action (CAPA #1, dated 1/2/2015) initiated to correct the cable from pulling out of the LaserCap's powerpack under conditions of normal use were not documented.

Your response is not adequate. Although it states that data sources will be reviewed by management on a regular basis as part of management review, you do not address conducting a retrospective review of these data sources to determine if there are any existing and potential causes of nonconforming product or other quality issues that have not been identified. Also, you did not provide a copy of the applicable procedures that address the type of statistical analysis that will be performed on each data source.

3. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). Specifically, your "Control of Non-Conforming Products, Processes, and Conditions" procedure, QMS-215 Rev A, dated 06/01/2013 is not being implemented.

For example, the FDA investigator's review of the incoming acceptance records for the laser boards received on 2/6/15, 2/9/15 and 2/12/15 revealed a total of 71 boards that were nonconforming. These nonconformances, including evaluation, any investigation, disposition, final review and signature are not documented on a Nonconforming Product/Process Report form, as required by your procedure.

Your proposed corrective action of recording all quarantined product on a Non-conformance Report (NCR) form and conducting training appears to be appropriate. Upon completion, please provide an example of a completed form and evidence that training has been completed.

4. Failure to document the results of the design verification, including the identification of the design, method(s), the date, and the individual(s) performing the verification, as required by 21 CFR 820.30(f). Specifically,

Your "LaserCap Design Requirement Inputs (Retrospective)" document, dated 06/01/2013 lists 10 of the design inputs were verified through "bench testing". There is no documentation of the dates of the tests, the results and who performed the test.

Your response is not adequate. The Verification Trace Matrix submitted only addresses safety related inputs. There are many inputs listed in your "LaserCap Design Requirement Inputs (Retrospective)" document, dated 06/01/2013, that are not addressed in this matrix. For example, your input document discusses the Outer Shell/Inner Liner Seal in section 1.1. Your response does not include verification testing to demonstrate the seal is moisture-proof.

5. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). Specifically, you did not implement your "Design Control" procedure, QMS-201 Rev A, dated 06/01/2013, section 6.7, for the design validation study for the LaserCap, in that:

a) There was no methods and acceptance criteria established.

b) The date of the study is not documented.

c) There was no documented assessment of the results of the survey that was part of the validation study to assure the devices conform to defined user needs and intended uses. The survey resulted in user's listing "undesirable" features, such as "connection sometimes is not good" and "wires way too delicate". There is no documented review of these "undesirable features" to determine if design changes were necessary.

Your proposed corrective actions appear to be appropriate. Upon completion, please provide a copy of the revised design control procedures and evidence that training has been completed.

6. Failure to maintain a complete risk analysis, as required by 21 CFR 820.30(g).

Specifically, section 6.6 "Risk Review" of your "Risk Analysis" procedure, QMS-217 Rev A, dated 06/01/2013, has not been implemented in that post-production data is not being evaluated to determine if the FMEA should be updated to reflect unidentified or changed hazards and if severity, probability and/or detection requires modification.

For example, the new hazard of "cable fraying and exposed wires" that was identified in the summer of 2014 due to complaints was not added to the FMEA until June 9, 2015 after the pre-announcement of the FDA inspection. An additional 6 hazards,regarding laser's failing, were added to the FMEA after a review of the complaints were completed during the FDA inspection.

Your proposed corrective actions appear to be appropriate. Upon completion, please provide a copy of the revised risk management and management review procedures.

7. Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specifications, as required by 21 CFR 820.50. Specifically, your "Approved Vendor Procedure", QMS-312 Rev A, dated 03/20/2015 and your "Supplier Quality Manager" procedure, QMS-202 Rev A, dated 06/01/2013 have not been implemented in that:

a) Only 3 of the 9 suppliers listed on your Approved Supplier List have a "Supplier Evaluation Forms", Form 202.2A , which documents the evaluation and the ability of the supplier to meet specified requirements. For the 3 suppliers that have these forms, they are incomplete and were not approved until 6/24/15.

b) The performance data from these suppliers is not compiled and reviewed, as required by section 6.3.1 of your "Supplier Quality Manager" procedure.

Your response cannot be assessed at this time, since the supplier evaluations have not yet been completed.

Please contact Gina Brackett, Compliance Officer at (513) 679-2700, ext. 2167 to schedule a regulatory meeting to discuss the distribution of your LaserCap device prior to the clearance of your 510(k) (K150613). Additionally, please be prepared to discuss any actions that you have taken or plan to take regarding the devices that are already in distribution that were being used to treat males, because the 510(k) clearance for this medical device is only to treat females. The 510 (k) clearance "Indication for Use" form (FORM FDA3881) states that the LaserCap LC PRO and LC ELITE are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I-II and Fitzpatrick Classification of skin phototypes of I-IV.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen working days from the date you receive this letter of the specific steps that you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about the content of this letter please contact Ms. Brackett at (513) 679-2700, ext. 2167, or by facsimile at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,
/S/
Toniette K. Williams
Acting District Director
Cincinnati District
Food and Drug Administration

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