DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969	1/5/2017-1/19/2017* FEI NUMBER 1000122259

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Susan A. Miller , President/CEO

FIRM NAME	STREET ADDRESS
P.C. Marketing, Inc.	1040 Wilt Ave
CITY, STATE, ZIP CODE, COUNTRY Ridgefield, NJ 07657-1512	TYPE ESTABLISHMENT INSPECTED Importer and Initial Distributor of Sunlamp Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATIONS PERTAINING TO THE QUALITY SYSTEM REGULATION AND THE MEDICAL DEVICE REPORTING REGULATION

OBSERVATION 1
Quality system procedures and instructions have not been established.

Specifically, the firm lacks written procedures appropriate to the scale and scope of its medical device operations, including but not limited to a management review procedure, quality audit procedure, document and record control procedure, training procedure, purchasing control / supplier management procedure, complaint handling procedure, corrective and preventive action procedure, and procedures for holding, distribution, servicing, and installation activities.

OBSERVATION 2
Written MDR procedures have not been developed and implemented.

Specifically, the firm lacks procedures for identifying, investigating, reporting, documenting, and filing medical device-related death, serious injury, and malfunction information.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	David H Smith, Investigator Esteban Beltran, Investigator 1/19/2017 X David H Smith David H Smith Investigator Signed by: David Smith -S	1/19/2017

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OBSERVATION 3

The importer failed to submit a report to the manufacturer on FDA Form 3500A within 30 days concerning information that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the firm has become aware from time to time that tanning beds which it has distributed have caught fire, including (b) (4) instances of uwe S-Class tanning beds which caught fire on or around the following dates:

(b) (4)

The firm has not submitted reports on Form FDA 3500A with information concerning these malfunctions.

OBSERVATION 4

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The organizational structure has not been established and maintained to ensure that devices are in accordance with 21 CFR 820.

Specifically, the firm's manager with executive responsibility has not appointed and documented the appointment of a quality system management representative, nor established responsibility, authority, and resources for personnel whose work bears upon product quality to train on and operate an adequate quality system.

OBSERVATION 5

Procedures for acceptance activities have not been established.

Specifically:
(a) The firm lacks written procedures for recording, documenting, and tracking the acceptance status of sun tanning beds, sunlamps, and parts.
(b) Good packaging material (b) (4) was observed being held for use in a (b) (4) (b) (4) area of the warehouse designated by (b) (4) together with (b) (4) (b) (4) material (b) (4) being held for disposal.
(c) Non-conforming products (b) (4) were observed being (b) (4) (b) (4) of the warehouse (b) (4) (b) (4) area. Non-acceptance status of items held there was indicated in (b) (4) (b) (4)

OBSERVATION 6

Complaint files are not adequately maintained.

Specifically, for seven (7) of (b) (4) instances of uwe S-Class tanning beds which it has distributed that have caught fire, the firm has complaint files which are limited to e-mail notification to the manufacturer, plus attached photographs and/or fire department incident reports if available. They do

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not contain determinations of Part 803 MDR reportability. They do not contain determinations of whether investigations are necessary, or documentation of decisions not to investigate. These seven (7) incidents were of S-Class units which caught fire on or around the following dates:

(b) (4)

For the remaining three (3) of (b) (4) S-Class fire incidents, the firm has no complaint files.

OBSERVATION 7

The manufacturer's formally designated complaint unit is located outside of the United States and complaint records are not reasonably accessible in the United States.

Specifically, the firm has not made available for review the complaint files of foreign medical device manufacturers whose devices it imports, as required of an initial distributor.

OBSERVATION PERTAINING TO ELECTRONIC PRODUCT RADIATION CONTROL PROVISIONS AND REGULATIONS

OBSERVATION 8

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The users' instructions for the sunlamp product did not contain a reproduction of the required label(s) prominently displayed at the beginning of the instructions.

Specifically, reproductions of the warning/recommended exposure, certification, and identification labels do not appear in the user manuals for products including but not limited to S-Class, Silver Bullet SE, Lotus, P90, iSun, iBed, and iDome Swing.

Additionally, the user manuals for S-Class, iSun, iDome, Lotus, and Silver Bullet SE products contain an incorrect version of the required statement from the warning/recommended exposure label, "If you do not tan in the sun, you are unlikely to tan from the use of this product." The incorrect version of the statement contained in S-Class, iSun, iDome, Lotus, and Silver Bullet SE user manuals reads as follows: "If you do not tan in the sun, you are likely to tan from the use of this product."

Annotations to Observations

Observation 1: *Promised to correct*
Observation 2: *Promised to correct*
Observation 3: *Under consideration*
Observation 4: *Promised to correct*
Observation 5: *Promised to correct*
Observation 6: *Promised to correct*
Observation 7: *Promised to correct*
Observation 8: *Corrected and verified*

****DATES OF INSPECTION***

1/05/2017(Thu),1/10/2017(Tue),1/11/2017(Wed),1/17/2017(Tue),1/19/2017(Thu)

1/19/2017

X Esteban Beltran
Esteban Beltran
Investigator
Signed by: Esteban Beltran -S

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
David H Smith, Investigator
Esteban Beltran, Investigator

1/19/2017
X David H Smith
David H Smith
Investigator
Signed by: David Smith -S

DATE ISSUED
1/19/2017

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."