

UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of:)
)
Center for Tobacco Products,)
)
Complainant,)
)
v.)
)
David Caldwell)
d/b/a Traverse Street Inn)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2013-H-0390
CRD Docket No. C-13-627

INTRODUCTION

1. The Center for Tobacco Products (CTP), Food and Drug Administration (FDA), United States Department of Health and Human Services, seeks a civil money penalty (CMP) in the amount of \$500 from David Caldwell d/b/a Traverse Street Inn (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently during a two-part inspection of the establishment conducted on December 17 and 18, 2012, FDA commissioned inspectors documented the following violations:
 - a. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c). Specifically, a person younger than 18 years of age was able to enter the establishment and approach a vending machine that sells tobacco products. In addition, Respondent told an FDA inspector that minors were permitted in the establishment when accompanied by a parent.

Therefore, this facility does not qualify as one where minors are not present or permitted to enter at any time; and

- b. Selling misbranded tobacco products through a vending machine, in violation of Section 301 of the Act (21 U.S.C. § 387c). Specifically, the establishment has a vending machine with selection buttons marked “Marlboro Lights” and “Camel Lights.” The cigarettes stocked to correspond with the “Marlboro Lights” and “Camel Lights” buttons are not labeled as such. Cigarettes with labels, labeling, or advertising that do not correspond to the actual product are misbranded under Section 903 of the Act (21 U.S.C. § 387c), in that the name on the button is false and/or misleading. In addition, the buttons use the terms “low in tar” and/or “lights”. Cigarettes with labels, labeling, or advertising that use the descriptors “low in tar” and/or “lights” are misbranded under Section 903 of the Act (21 U.S.C. § 387c), in that the descriptive terms are false and/or misleading. Labeling or advertising cigarettes as “low in tar” and/or “lights” is misleading to consumers. Congress has found many smokers mistakenly believe that “low in tar” and/or “lights” cigarettes cause fewer health problems than other cigarettes

Details regarding the case history are included in Paragraphs 9 - 11 below.

2. Respondent owns an establishment that sells tobacco products, which does business under the name Traverse Street Inn, located at 73 Traverse Street, Athol, MA 01331.

LEGAL AUTHORITY

3. FDA has the authority to seek civil money penalties from any person who violates a requirement of the Act related to tobacco products. 21 U.S.C. § 333(f)(9).
4. The Act prohibits the misbranding of a tobacco product while such product is held for sale after shipment of the product or its components in interstate commerce. 21 U.S.C. § 331(k).
5. A tobacco product is deemed to be misbranded if it is sold or distributed in violation of regulations issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b).
6. The regulations at 21 C.F.R. Part 1140 were issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). Therefore, selling or distributing a tobacco product in violation of these regulations causes that tobacco product to be misbranded.
7. A tobacco product is deemed to be misbranded pursuant to Section 903 of the Act (21 U.S.C. § 387c) if its labeling or advertising is false or misleading in any particular.
8. FDA has documented multiple violations of 21 C.F.R. Part 1140 and one violation of 21 U.S.C. § 387c at Respondent's establishment, as detailed below.

CASE HISTORY

9. FDA-commissioned inspectors have completed inspections of Respondent's establishment twice in a twelve month period. The inspectors documented violations during both inspections.
10. Previously, on July 26, 2012, CTP issued a Warning Letter to Traverse Street Inn. The Warning Letter stated that an FDA-commissioned inspector observed a

violation at the establishment on April 13, 2012, for using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c). The Warning Letter stated that failure to correct the violation may result in a civil money penalty action, or other regulatory action by FDA. It also stated that it was the responsibility of Traverse Street Inn to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.

11. On July 31, 2012, by telephone, David Caldwell, owner of Traverse Street Inn, responded to the Warning Letter. Mr. Caldwell stated he would have the vending machine company remove the machine from his establishment. CTP responded to David Caldwell by letter dated August 14, 2012, acknowledging receipt of the establishment's response and reminding Traverse Street Inn of its continuing obligation to be in compliance with the Act and its implementing regulations.

PROPOSED PENALTY

12. Retailers who have violated regulations promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)) may incur a civil money penalty up to the amounts provided in the following table:

Number of Violations	Civil Money Penalty
1	\$0.00 w/ warning letter
2 within a 12 month period	\$250
3 within a 24 month period	\$500
4 within a 24 month period	\$2,000
5 within a 36 month period	\$5,000
6 within a 48 month period	\$10,000

See 21 C.F.R. § 17.2; *Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers*, November 2012

(available at

<http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>).

13. Retailers who have committed violations of Section 903 of the Act (21 U.S.C. § 387c) may incur a civil money penalty up to \$15,000 per violation, and not to exceed \$1,000,000 for all violations in a single proceeding. 21 U.S.C. § 333(f)(9)(A).

14. CTP requests that a civil money penalty in the amount of \$250 be assessed against Respondent for two violations of 21 C.F.R. Part 1140 within a twelve month period and \$250 for one violations of Section 903, a total penalty fee of \$500.

OPTIONS FOR RESPONDING TO COMPLAINT

15. Respondent must take one of the following three actions within the time listed below:
 - a. Acknowledge that the violations occurred and pay the penalty: To pay the penalty, Respondent should follow the instructions detailed in the cover letter. The signed Acknowledgment Form must be received by CTP within 15 days after service of the Complaint. Following receipt of the signed Acknowledgment Form, CTP will contact the Respondent to provide the payment instructions. Respondent should not send any payments to CTP before receiving the specific payment instructions from CTP.
 - b. File an Answer: Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. The Answer shall be deemed to be a request for a hearing, unless the Answer states otherwise. The failure to file an Answer within 30 days after service of the Complaint may result in the imposition of the proposed civil money penalty. 21 C.F.R. § 17.11. Instructions for filing an Answer are listed in Paragraph 18. After filing an Answer, Respondent may choose to participate in discussions with FDA to try to reach a settlement.

- c. Request an Extension: Respondent has the right to request an extension of time to file an Answer, for good cause. This request must be made within 30 days after service of the Complaint. Instructions for filing for an extension are listed in Paragraphs 21 and 22.
16. Respondent has the right, but is not required, to retain counsel for representation.

INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING

17. Rules for drafting and filing the Answer can be found at 21 C.F.R. § 17.9.
18. If filing an Answer, the Answer:
- a. Must be filed with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS 6132), ATTN: FDA CMP, Washington, D.C. 20201. The Answer must include both the FDA Docket Number and CRD Docket Number which are found at the top of this document.
 - b. Must include the following:
 - i. Admission or denial of each of the allegations of liability found in this Complaint, including specifically the allegations in Paragraphs 1 – 2 and 10 – 11. Allegations not specifically denied in the Answer will be considered admitted;
 - ii. All defenses on which Respondent intends to rely;
 - iii. All reasons (if any) why Respondent contends that the penalty should be less than the amount stated in Paragraph 14. Examples include: any retailer training program you have, any state penalty

you paid for this alleged violation, or reasons you are unable to pay the penalty; and

- iv. The name, address, and telephone number of Respondent's counsel (if any). Other contact information, such as e-mail address, may be included.

c. May also include the following:

- i. Information (if any) regarding penalties paid to a State for the same violation(s) charged in this Complaint. FDA will consider this information for purposes of determining a civil money penalty.

Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, November 2012.

- ii. A request for an informal Settlement Conference to discuss reducing the penalty amount owed. Such a request must be filed as a part of the Answer, and is not an alternative to filing a complete Answer. If an informal Settlement Conference results in an agreed payment of a reduced penalty and written acknowledgment by the Respondent that the violations occurred, a hearing would no longer be necessary.

19. If, after the Answer is filed, Respondent needs to change the Answer, Respondent can do so by filing a motion with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS 6132), ATTN: FDA CMP, Washington, D.C. 20201. 21 C.F.R. §

17.9(d). The motion must include both the FDA Docket Number and CRD Docket Number which can be found at the top of this document.

20. The failure to file an Answer or make full payment within 30 days after service of the Complaint may result in the imposition of the proposed civil money penalty. 21 C.F.R. § 17.11.

INSTRUCTIONS FOR FILING A REQUEST FOR AN EXTENSION

21. Within 30 days after service of the Complaint, Respondent may request an extension of time to file an Answer. 21 C.F.R. § 17.9(c).
22. The request for an extension should be filed with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS 6132), ATTN: FDA CMP, Washington, D.C. 20201. The request must include both the FDA Docket Number and CRD Docket Number.
23. The Administrative Law Judge may grant Respondent up to 30 additional days to file an Answer, if good cause is shown. 21 C.F.R. § 17.9(c).

REQUEST FOR RELIEF

24. CTP respectfully requests that an order assessing a civil money penalty against Respondent in the amount of \$500 be entered.

DATED: April 4, 2013

Respectfully submitted,

/s/

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