

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.)
)
McCabe's Tavern, Inc.,)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2012-H-0918
CRD Docket No. C-12-1164

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 in the amount of \$2,250 from McCabe's Tavern, Inc. (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently during a two-part inspection of the establishment conducted on March 21 and 23, 2012, FDA commissioned inspectors documented the following violations:
 - a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a).

Specifically, a person younger than 18 years of age was able to purchase a package of Camel Filters cigarettes from your vending machine on March 21, 2012, at approximately 5:21 PM MT;
 - b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by

- 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale, as detailed above, on March 21, 2012, at approximately 5:21 PM MT;
- c. 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 purchase a tobacco product from the vending machine. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time. Additionally, Mr. Greg Howard told the inspector that minors are permitted to enter the establishment before 9 PM if accompanied by an adult; and
 - d. Selling misbranded tobacco products through a vending machine, in violation of 21 U.S.C. § 387c. Specifically, the establishment has a vending machine with selection buttons marked "Marlboro Lights," "Marlboro Lights 100's," "Marlboro Ultra Lights," and "Marlboro Ultra Lights 100's." The cigarettes stocked to correspond with the "Marlboro Lights" button 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 a label, labeling, or advertising for the corresponding cigarettes that is false and/or misleading. In addition, the buttons use the term "light." Cigarettes with labels, labeling, or advertising that use the descriptor "light" are misbranded under Section 903 of the Act (21 U.S.C. § 387c), in that the descriptive term is false and/or misleading. Labeling or advertising cigarettes as "light" is misleading to consumers.

Congress has found many smokers mistakenly believe that “light” cigarettes cause fewer health problems than other cigarettes.

Details regarding the relevant inspectional history are included in Paragraphs 9-10 below.

2. Respondent owns an establishment that sells tobacco products, which does business under the name McCabe’s Tavern, Inc., located at 520 South Tejon Street, Colorado Springs, CO 80903.

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 if its labeling or advertising is false or misleading in any particular. 21 U.S.C. § 387c.
8. FDA has documented multiple violations of 21 C.F.R. Part 1140 and 21 U.S.C. § 387c at Respondent’s establishment, as detailed below.

PREVIOUS INSPECTION HISTORY

9. FDA-commissioned inspectors have inspected Respondent's establishment twice in a 24 month period. The inspectors documented violations during both inspections.
10. Previously, on October 20, 2011, CTP issued a Warning Letter to McCabe's Tavern. The Warning Letter stated that an FDA-commissioned inspector observed violations at the establishment on August 4, 2011, including:
 - a. Failure to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without the assistance of any electronic or mechanical device in a facility that does not ensure that no person younger than 18 years of age is present or permitted to enter, at any time, as required by 21 C.F.R. §§ 1140.14(c) and 1140.16(c); and
 - b. Failure to ensure that all violative items are removed or brought into compliance with the requirements of 21 C.F.R. Part 1140, as required by 21 C.F.R. § 1140.14(e).

The Warning Letter stated that failure to correct the violations may result in a civil money penalty action, or other regulatory action by FDA. It also stated that it was the responsibility of McCabe's Tavern to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.

11. FDA did not receive a response to the Warning Letter. UPS records show that the Warning Letter was received on October 21, 2011, by "HOWARD."

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*, March 2011

(available at

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

13. Retailers who have committed violations of Section 903 (21 U.S.C. § 387c) of the Act 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 \$2,000 be assessed against Respondent for four violations of 21 C.F.R. Part 1140 within a twenty-four month period and \$250 for one violation of section 903, a total penalty fee of \$2,250.

OPTIONS FOR RESPONDING TO COMPLAINT

15. Within 30 days of service of this Complaint, Respondent must take one of the following three actions:
 - a. Pay the Penalty: To pay the penalty, Respondent should contact Adriana Gibson at (301) 796-9194 for further instructions.
 - b. File an Answer: Respondent has the right to request a hearing by filing an Answer. 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 of 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. 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 BOTH the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, HFA-305, Rockville, MD 20852 AND 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. 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*, March 2011.
 - ii. A request for an informal Settlement Conference to discuss reducing the penalty amount owed. Such a request is to 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, 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 BOTH the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, HFA-305, Rockville, MD 20852 AND 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 of 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 of receiving 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 BOTH the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, HFA-305, Rockville, MD 20852 AND 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 \$2,250 be entered.

DATED: August 21, 2012

Respectfully submitted,

/s/

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