

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.)
)
Fred Meyer Stores, Inc.)
d/b/a Fred Meyer #652)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2012-H-0717
CRD Docket No. C-12-972

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 \$250 from Fred Meyer Stores, Inc. d/b/a Fred Meyer #652 (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act) by selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a).
2. Respondent owns an establishment that sells tobacco products, which does business under the name Fred Meyer #652, located at 201 South Water Street Ellensburg, WA 98926.

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. FDA has documented multiple violations of 21 C.F.R. Part 1140 at Respondent's establishment, as detailed below.

HISTORY OF VIOLATIONS

8. FDA-commissioned inspectors have inspected Respondent's establishment twice, the first occurred on October 26, 2011. The inspectors documented violations during both inspections.
9. Most recently, during a two-part inspection of the establishment at 201 South Water Street, Ellensburg, WA, conducted on March 9 and 20, 2012, the inspector documented a violation for 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 Menthol cigarettes on March 9, 2012, at approximately 4:47 PM.
10. Previously, on December 29, 2011, CTP issued a Warning Letter to Fred Meyer Stores, Inc d/b/a Fred Meyer #652. The Warning Letter stated that an FDA-

commissioned inspector observed a violation at the establishment on October 26, 2011, including the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). 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 Fred Meyer Stores, Inc d/b/a Fred Meyer #652 to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.

11. CTP received the following responses to the Warning Letter:
 - a. On December 30, 2011, Kelly Hart, Operations Manager, contacted CTP by phone to ask about the name of the clerk who sold cigarettes to a minor. A CTP employee told Ms. Hart that CTP does not routinely collect that information, and gave her the approximate time the sale occurred. Ms. Hart stated she would write a letter describing the steps that would be taken to avoid future violations;
 - b. Mike Howe, District Operations Coordinator, responded by both phone and email on January 12, 2012. Mr. Howe initially wanted to know if the Warning Letter was sent to both the corporate office and the retail establishment. He was informed that both locations were sent a copy of the Warning Letter. The same day, Mr. Howe emailed CTP to obtain more information regarding the purchase. CTP responded by email on January 13, 2012, with details from the Warning Letter, and the approximate time of sale; and

c. Through an undated letter, Ryan Cheney, Store Director, stated that the employee responsible for the sale would be disciplined. He also stated that in support of the responsible marketing and sale of tobacco, Kroger had entered into an Assurance of Voluntary Compliance (AVC) contract with the attorneys general from the four states where Fred Meyer stores operate, including Washington. Mr. Cheney also indicated that Fred Meyer employees receive training regarding the sale of tobacco products annually and at the time of hire. In addition to training, Mr. Cheney stated that the stores are subject to random audits, and store registers are equipped with prompts that require associates to enter the purchaser's age at the time of sale.

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. 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.

OPTIONS FOR RESPONDING TO COMPLAINT

14. 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 Timothy Mueller at (301) 796-8775 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 17. 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 20 and 21.
15. Respondent has the right, but is not required, to retain counsel for representation.

INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING

16. Rules for drafting and filing the Answer can be found at 21 C.F.R. § 17.9.
17. 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 in Paragraphs 9 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 13. 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.

18. 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.

19. 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

20. 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).
21. 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.
22. 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

23. CTP respectfully requests that an order assessing a civil money penalty against Respondent in the amount of \$250 be entered.

DATED: July 6, 2012

Respectfully submitted,

/s/

Michael D. Helbing
Attorney for Complainant
Center for Tobacco Products
United States Food and Drug
Administration
10903 New Hampshire Avenue
WO31-4570
Silver Spring, MD 20993-0002
Phone: (301) 796-8620
Fax: (301) 847-8618
Email: Michael.Helbing@fda.hhs.gov