

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

Center for Tobacco Products, Complainant,)	
v.)	
Lynda Patterson d/b/a Tobacco Warehouse #8,)	
Respondent.)	
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**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2012-H-0628
CRD Docket No. C-12-850

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 \$500 from Lynda Patterson, d/b/a Tobacco Warehouse #8 (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act) by:
 - a. Using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)(1); and
 - b. Failing to remove all violative items or bring them into compliance, as required by 21 C.F.R. § 1140.14(e).

2. Respondent owns an establishment that sells tobacco products, which does business under the name Tobacco Warehouse #8, located at 810 North Central Avenue, Batesville, AR 72501.

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 the Respondent's establishment twice, the first occurred on June 10, 2011. The inspectors documented violations during both inspections.
9. Most recently, during a two-part inspection of the establishment at 810 North Central Avenue, Batesville, AR, conducted on February 1 and 8, 2012, the inspector documented the following violations:
 - a. Using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)(1). Specifically, the establishment has self-service displays of

loose cigarette tobacco in a customer accessible part of the establishment.

During the inspection, the clerk informed the inspector that minors were permitted in the establishment with a parent. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time; and

- b. Failing to remove all violative items or bring them into compliance, as required by 21 C.F.R. § 1140.14(e).
10. Previously, on September 22, 2011, CTP issued a Warning Letter to Tobacco Warehouse. The Warning Letter stated that an FDA-commissioned inspector observed violations at the establishment on June 10, 2011, including:
- a. Failure to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without ensuring 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. §§ 1140.16(c)(1) and 1140.16(c)(2)(ii); and
 - b. Failure to ensure that all violative items are removed or are brought into compliance with 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 Tobacco Warehouse 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 September 23, 2011 by "Smith."

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 \$500 be assessed against the Respondent for 3 violations of 21 C.F.R. Part 1140 within a twenty-four 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 9-10.
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 \$500 be entered.

DATED: **June 18, 2012**

Respectfully submitted,

/s/

Marci B. Norton
Attorney for Complainant
Center for Tobacco Products
United States Food and Drug
Administration
White Oak, Bldg. 31, Room 4510
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(301) 796-8580 (phone)
(301) 847-8638 (fax)
marci.norton@fda.hhs.gov