

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.)
)
Energy Marketing 245, LLC)
d/b/a Energy Express/Phillips 66,)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2013-H-1196
CRD Docket No. C-13-1401

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 \$2,000 from Energy Marketing 245, LLC, d/b/a Energy Express/Phillips 66 (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently during a two-part inspection of the establishment conducted on April 25 and May 22, 2013, 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 Newport Box cigarettes on April 25, 2013, at approximately 7:57 PM; and

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 April 25, 2013, at approximately 7:57 PM.

Details regarding the case history are included in Paragraphs 9 – 13 below.

2. On May 1, 2013, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on April 25, 2013, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 7:57 PM. This Notice stated that other potential violations of federal tobacco law may have been observed, and further stated that if, after review, CTP determined that there was a violation of federal law, the establishment may receive further notification from FDA.
3. Respondent owns an establishment that sells tobacco products, which does business under the name Energy Express/Phillips 66, located at 733 South Vandeventer, Saint Louis, MO 63110.

LEGAL AUTHORITY

4. 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).
5. 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).

6. 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).
7. 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.
8. FDA has documented multiple violations of 21 C.F.R. Part 1140 at Respondent's establishment, as detailed below.

CASE HISTORY

9. FDA-commissioned inspectors have completed inspections of Respondent's establishment three times in a twenty-four month period. The inspectors documented violations during all of the inspections.
10. Previously, on February 8, 2013, CTP initiated a civil money penalty action, FDA Docket Number FDA-2013-H-0128, CRD Docket Number C-13-372, against Energy Marketing 245, LLC d/b/a Energy Express/Phillips 66 for a violation of 21 C.F.R. Part 1140. That Complaint listed the following violation documented during an inspection conducted on June 19 and 25, 2012, 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 Newport cigarettes on June 19, 2012, at approximately 3:11 PM. Additionally, on June 27, 2012, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on June 19, 2012, and that during this inspection a minor was able to enter the establishment and

purchase a regulated tobacco product at approximately 3:11 PM. This Notice stated that other potential violations of federal tobacco law may have been observed, and further stated that if, after review, CTP determined that there was a violation of federal law, the establishment may receive further notification from FDA.

11. The action described in the preceding paragraph concluded with Energy Marketing 245, LLC d/b/a Energy Express/Phillips 66 paying the penalty and the court closing the case on March 12, 2013.
12. Previously, on April 19, 2012, CTP issued a Warning Letter to Energy Express/Phillips 66. The Warning Letter stated that an FDA-commissioned inspector observed a violation at the establishment on March 6, 2012, 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 Newport cigarettes on March 6, 2012, at approximately 7:30 PM CT. 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 Energy Express/Phillips 66 to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.
13. On May 7, 2012, by telephone, Clay Bawne, District Manager, responded to the Warning Letter on behalf of Respondent. Mr. Bawne stated that all employees were retrained to card customers who appear to be under the age of 40 and to not sell tobacco products to anyone under the age of 18. CTP responded to Clay Bawne by letter dated May 29, 2012, acknowledging receipt of the

establishment's response and reminding Energy Express/Phillips 66 of its continuing obligation to be in compliance with the Act and its implementing regulations.

PROPOSED PENALTY

14. 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>).

15. 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.

OPTIONS FOR RESPONDING TO COMPLAINT

16. Respondent must take one of the following four 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 Respondent to provide the payment instructions. Respondent should not send any payments to CTP before receiving the specific payment instructions from CTP. Payment must be received by CTP within 30 days after service of the Complaint or Respondent must either file an Answer to the Complaint (see option (c) below) or request an extension of time for filing the Answer (see option (d) below).
- b. Request Settlement: Respondent may choose to participate in discussions with CTP to reach a settlement of this matter. If after a Settlement Conference, Respondent submits written acknowledgment of the violations and pays an agreed-upon penalty amount, a hearing would no longer be necessary. Payment must be received by CTP within 30 days after service of the Complaint or Respondent must either file an Answer to the Complaint

(see option (c) below) or request an extension of time for filing the Answer (see option (d) below).

- c. 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 19.
- d. 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 22 and 23.

- 17. Respondent has the right, but is not required, to retain counsel for representation.

INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING

- 18. Rules for drafting and filing the Answer can be found at 21 C.F.R. § 17.9.
- 19. 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 1-3 and 10-13. 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 15. Examples include: any retailer training program Respondent has, any state penalty Respondent paid for this alleged violation, or reasons Respondent is 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 may 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 Respondent that the violations occurred, a hearing would no longer be necessary.

20. 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.
21. 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

22. 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).
23. 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.
24. 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

25. CTP respectfully requests that an order assessing a civil money penalty against Respondent in the amount of \$2,000 be entered.

DATED: September 23, 2013

Respectfully submitted,

/s/

Deeona Gaskin

Attorney for Complainant

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