

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. )  
 )  
Ashok Patel / Al Patel / Arya Ventures )  
d/b/a Exxon / Casco One Stop, )  
 )  
Respondent. )  
\_\_\_\_\_

**ADMINISTRATIVE COMPLAINT  
FOR CIVIL MONEY PENALTIES**

FDA Docket No. FDA-2014-H-0837  
CRD Docket No. C-14-1343

**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 \$250 from Ashok Patel / Al Patel / Arya Ventures, d/b/a Exxon / Casco One Stop (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently during an inspection of the establishment conducted on January 29, 2014, an FDA-commissioned inspector documented a violation for using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c). Specifically, the establishment had customer-accessible displays of Rave and Gambler brands of cigarette tobacco. The establishment failed to ensure that minors are neither present nor permitted to enter at any time, as the establishment is open to the general public during business hours. Therefore, this facility does not qualify as one where minors are

not permitted to enter at any time. 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 Exxon / Casco One Stop, located at 313 Main Street, Casco, WI 54205.

### **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.

### **CASE HISTORY**

8. FDA-commissioned inspectors documented violations during two inspections at Respondent's establishment within a twelve month period.

9. Previously, on November 7, 2013, CTP issued a Warning Letter to Exxon/Casco One Stop. The Warning Letter stated that an FDA-commissioned inspector observed a violation at the establishment on September 10, 2013, for using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c). Specifically, the establishment had Gambler brand cigarette tobacco for sale that was located on the counter in an area that is open to customers. The establishment failed to ensure that minors were neither present nor permitted to enter at any time as the establishment was open to the general public during business hours; therefore, this facility did not qualify as one where minors are not permitted to enter at any time. 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 Exxon/Casco One Stop to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.
10. On November 12, 2013, by telephone, Al Patel, who identified himself as the owner of Casco One Stop, responded to the Warning Letter on behalf of Respondent. Mr. Patel stated that he removed the tobacco products from the counter and that someone must have accidentally left the tobacco products on the counter because it is the establishment's normal procedures to place tobacco products behind the counter. CTP responded to Al Patel by letter dated November 26, 2013, acknowledging receipt of the establishment's response and reminding Exxon/Casco One Stop of its continuing obligation to be in compliance with the Act and its implementing regulations.

**PROPOSED PENALTY**

11. 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*, September 2013

(available at

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

12. 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

13. 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. Respondent should not send any payments to CTP before submitting the Acknowledgment Form, which must be submitted within 15 days after service of the Complaint. 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 an 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 16.

- 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 19 and 20.
14. Respondent has the right, but is not required, to retain counsel for representation.

**INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING**

15. Rules for drafting and filing the Answer can be found at 21 C.F.R. § 17.9.
16. 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 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 12. Examples include: any retailer training program Respondent has put in place, 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, September 2013.*
  - 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.

17. 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.
18. 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**

19. 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).
20. 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.
21. 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**

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

DATED: June 23, 2014

Respectfully submitted,

/s/

---

**Annamarie Kempic**  
Attorney for Complainant  
Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Phone: (877) 287-1373  
Fax: (301) 827-5370  
[CTP-Compliance-CMP-  
Correspondence@fda.hhs.gov](mailto:CTP-Compliance-CMP-Correspondence@fda.hhs.gov)