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,	)	
	)	**ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTIES**
v.	)	
	)	
Diyap, LLC d/b/a Sunny Wine and Spirit,	)	FDA Docket No. FDA-2015-H-1975 CRD Docket No. C-15-2728
	)	
Respondent.	)	
	)	

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 $500 from Diyap, LLC, d/b/a Sunny Wine and Spirit (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently, during a two-part inspection of the establishment conducted on February 11 and March 4, 2015, 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 Marlboro Gold Pack cigarettes on February 11, 2015, at approximately 11:14 AM; 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 February 11, 2015, at approximately 11:14 AM.

Details regarding the case history are included in Paragraphs 9-11 below.

2. On February 13, 2015, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on February 11, 2015, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 11:14 AM. 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 Sunny Wine and Spirit, located at 15 Mechanics Street, Putnam, CT 06260.

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 documented violations during two inspections at Respondent's establishment within a twenty-four month period.

10. Previously, on June 19, 2014, CTP issued a Warning Letter to Sunny's Wine and Spirits. The Warning Letter stated that an FDA-commissioned inspector observed violations at the establishment on April 25, 2014, including:

    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 Marlboro Red Label 100's cigarettes on April 25, 2014, at approximately 12:00 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, 2014, at approximately 12:00 PM.

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 Sunny's Wine and Spirits to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations. Additionally, on April 30, 2014, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on April 25, 2014, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 12:00 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. On June 22, 2014, by letter, Vimalkumar Patel, who identified himself as the establishment's owner, responded to the Warning Letter on behalf of Respondent. Mr. Patel stated, "I accepted this violation." Mr. Patel also stated that Respondent's procedure is to verify the identification of individuals younger than 27 years of age. Mr. Patel further stated that Respondent follows all FDA rules and regulations regarding tobacco products. CTP responded to Mr. Patel by letter dated July 29, 2014, acknowledging receipt of the establishment's response and reminding Sunny's Wine and Spirit of its continuing obligation to be in compliance with the Act and its implementing regulations.

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 or subsequent within a 48 month period	$11,000

See 21 C.F.R. § 17.2; *Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers*, June 2014 (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 Respondent for three violations of 21 C.F.R. Part 1140 within a twenty-four month period.

OPTIONS FOR RESPONDING TO COMPLAINT

14. 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 17.

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 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 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 10-11. 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 Respondent has put in place, 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*, June 2014.

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 the Respondent that the violations occurred, 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 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 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

20. 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).

21. 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.

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 10, 2015

Respectfully submitted,

/s/

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