

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

Center for Tobacco Products)	
)	
Complainant,)	
)	
v.)	ADMINISTRATIVE COMPLAINT
)	FOR CIVIL MONEY PENALTIES
Ken V Inc.)	FDA Docket No. FDA-2012-H-0810
d/b/a Kenny's Bar & Grill)	CRD Docket No. C-12-1053
)	
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 in the amount of \$2,000 from Ken V Inc., d/b/a Kenny's Bar & Grill (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act) by:
 - a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a);
 - 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); and
 - c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c).
2. Respondent owns an establishment that sells tobacco products, which does business under the name Kenny's Bar & Grill, located at 7045 Highway 61- 67, Barnhart, MO 63012.

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 August 18, 2011. The inspectors documented violations during both inspections.
9. Most recently, during a two-part inspection of the establishment at 7045 Highway 61-67, Barnhart, MO, conducted on February 15 and March 19, 2012, the inspector 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 Red Label cigarettes from a vending machine in Respondent's establishment on February 15, 2012, at approximately 5:13 PM CST;

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 15, 2012, at approximately 5:13 PM CST; and

c. Using a vending machine in a non-exempt facility, in violation of 21 C.F.R. § 1140.14(c). Specifically, a person younger than 18 years of age was able to enter the establishment and purchase a tobacco product from the vending machine. In addition, the manager on duty informed the inspector that minors are permitted in the establishment when accompanied by an adult.

Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

10. Previously, on December 1, 2011, CTP issued a Warning Letter to Kenny's Bar & Grill, at 7125 Metropolitan Boulevard #109, Barnhart, MO 63012. The Warning Letter stated that an FDA-commissioned inspector observed violations at the establishment on August 18, 2011, including:

a. Failure to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without the assistance of any electronic or mechanical device in a facility that does not ensure 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.

§§ 1140.14(c) and 1140.16(c); and

- b. Failure to remove all violative items or bring them into compliance, 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 Kenny's Bar & Grill to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.

11. Between FDA's initial inspection of the establishment, on August 18, 2011, and the date the Warning Letter was issued on December 1, 2011, the establishment moved from 7125 Metropolitan Boulevard #109, Barnhart, MO to 7045 Highway 61-67, Barnhart, MO. CTP became aware of the change in address after it attempted delivery at the 7125 Metropolitan Boulevard address. CTP re-issued the Warning Letter to Kenny's Bar & Grill at the 7045 Highway 61-67 address.
12. A Notice of Inspection was issued to Deborah S. Woody during the initial inspection of the establishment on August 18, 2011. UPS records show that the Warning Letter was received on December 9, 2011, at 7045 Highway 61-67, Barnhart, MO and signed for by "D. Woody." FDA did not receive a response to the Warning Letter.

PROPOSED PENALTY

13. 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>).

14. 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

15. 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 18. 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 21 and 22.
16. Respondent has the right, but is not required, to retain counsel for representation.

INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING

17. Rules for drafting and filing the Answer can be found at 21 C.F.R. § 17.9.
18. 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 of liability, including specifically Paragraphs 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 14. 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.
19. 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.
20. 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

21. 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).
22. 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.

23. 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

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

DATED: July 31, 2012

Respectfully submitted,

/s/

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