

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 of which occurred on May 9, 2011. The inspectors documented violations during both inspections.
9. Most recently, during a two-part inspection of the establishment at 2009 Rainier Avenue South, Seattle, WA 98144, conducted on September 9 and 27, 2011, the inspector documented the following violation:
 - 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 Camel Blue cigarettes on September 9, 2011.
10. Previously, on July 7, 2011, CTP issued a Warning Letter to Tung Enterprises Inc., d/b/a 7-Eleven #24497. The Warning Letter stated that an FDA-commissioned inspector observed violations at the establishment on May 9, 2011, including:

- a. Sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a); and
- b. Failure to verify by means of photographic identification, containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age, as required by 21 C.F.R. § 1140.14(b)(1). No such verification is required for any person over the age of 26, as per 21 C.F.R. § 1140.14(b)(2).

The Warning Letter also stated that failure to correct the violations may result in a civil money penalty action, or other regulatory action by FDA. It further stated that it was the responsibility of Tung Enterprises Inc., d/b/a 7-Eleven #24497 to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations.

11. On July 11, 2011, by telephone, Rajinder Tung responded to the Warning Letter on behalf of Respondent. Mr. Tung stated that it is the establishment's policy to request identification from anyone under 27 years of age and that he would re-train all employees on this policy.

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 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 \$250.00 be assessed against Respondent for two violations of 21 C.F.R. Part 1140 within a twelve month period.

OPTIONS FOR RESPONDING TO COMPLAINT

14. Within 30 days of receiving service of this Complaint, Respondent must take one of the following three actions:
 - a. Pay the penalty: To pay the penalty, Respondent should contact Marguerite Lee at (301) 796-8573 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, Room1061, 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 9-11. 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 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, Room1061, 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, Room1061, 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 \$250.00 be entered.

DATED: **December 2, 2011**

Respectfully submitted,

/s/

Sonia W. Nath

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