

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.)
)
Mei Lan Liu)
d/b/a Yin Hua Lou Restaurant,)
)
Respondent.)

**ADMINISTRATIVE COMPLAINT
FOR NO-TOBACCO-SALE ORDER**

FDA Docket No. FDA-2016-R-2489
CRD Docket No. T-16-1651

INTRODUCTION

1. The Center for Tobacco Products (“CTP”), Food and Drug Administration (“FDA”), United States Department of Health and Human Services, seeks to have the Secretary impose a no-tobacco-sale order (“NTSO”) for a period of 30 calendar days on Mei Lan Liu, d/b/a Yin Hua Lou Restaurant (Respondent) for repeatedly violating FDA’s tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (“Act”) (21 U.S.C. § 387f(d)). As described in more detail below, FDA-commissioned inspectors observed six repeated violations of FDA’s tobacco regulations over a 36-month period, as shown in the following table:¹

¹ The table identifies only Respondent’s violations of regulations promulgated under Section 906(d) of the Act, 21 U.S.C. § 387f(d), and excludes any repeated violations that occurred outside of the 36-month period and any violations of other Act sections that are not at issue in this case.

Charged Violation ^{2, 3}	Violative Inspection Dates				Number of Repeated Violations
	04/18/2012	03/13/2013	02/09/2014	11/11/2015	
Selling cigarettes / cigarette tobacco / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a) / 21 C.F.R. § 1140.14(a)(1)	OV	X	X	X	3
Failing to verify ID for cigarettes / cigarette tobacco / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1) / 21 C.F.R. § 1140.14(a)(2)(i)	OV	X	X	X	3
FDA Action	First CMP Initiated 08/07/2012 FDA-2012-H-0834 C-12-1076	Second CMP Initiated 09/25/2013 FDA-2013-H-1115 C-13-1308	Third CMP Initiated 01/02/2015 FDA-2014-H-2281 C-15-759	Current Complaint	Total: 6 Repeated Violations

LEGAL AUTHORITY

2. FDA has the authority to impose an NTSO prohibiting the sale of tobacco products at a retail outlet on any person who commits repeated violations of requirements promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)).
- 21 U.S.C. § 333(f)(8). “Repeated violations” is defined as at least five violations

² “OV” indicates an original violation. “X” indicates a repeated violation.

³ As of August 8, 2016, the effective date of FDA’s Final Rule Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, available at <https://federalregister.gov/a/2016-10685> (hereafter, “Deeming Regulation”), the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained the same. The chart includes references to the original and new citations; CTP counts as a “repeated violation” an action that violates the same textual regulation, regardless of whether the specific citation for such violation has changed.

of particular requirements over a 36-month period at a particular retail outlet.

See Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009).

3. 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).
4. 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).
5. 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.
6. Retailers who have committed five or more repeated violations of particular requirements promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)) within a 36-month period are subject to an NTSO for a period provided in the following table:

Number of NTSOs received by Retailer	Maximum Period of Time for NTSO
First NTSO	30 Calendar Days
Second NTSO	6 Months
Third (and subsequent) NTSO	Permanent NTSO

See CTP, U.S. FDA., U.S. Dep't of Health & Human Servs., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order (August 2015), *available at*

<http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

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

CURRENT ALLEGATIONS

8. Respondent owns an establishment that does business under the name Yin Hua Lou Restaurant, located at 1603 West Erie Avenue, Philadelphia, PA 19140.
9. Respondent's establishment receives tobacco products in interstate commerce, including Newport Box 100s cigarettes and Newport Menthol Gold Box cigarettes, and holds them for sale after shipment in interstate commerce.
10. On November 11, 2015, an FDA-commissioned inspector conducted an inspection of Yin Hua Lou Restaurant. During that inspection, Respondent committed the following violations:
 - a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on November 11, 2015, at approximately 1:43 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(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on November 11, 2015, at approximately 1:43 PM.

PREVIOUS CASE HISTORY

11. Respondent has been the subject of three prior CTP Civil Money Penalty (“CMP”) actions based on its violations of the Act.
12. On January 2, 2015, CTP initiated its most recent CMP action against Respondent, alleging that FDA-commissioned inspectors documented the following violations at Respondent’s establishment:
 - a. Sale to a minor (21 C.F.R. § 1140.14(a)) on February 9, 2014, March 13, 2013, and April 18, 2012; and
 - b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer’s date of birth (21 C.F.R. § 1140.14(b)(1)) on February 9, 2014, March 13, 2013, and April 18, 2012.

See Compl., FDA Docket Number FDA-2014-H-2281, CRD Docket Number C-15-759. The CMP Action was closed after Mei Lan Liu d/b/a Yin Hua Lou Restaurant admitted all of the allegations in the Complaint and paid the agreed-upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Attachment to Notice of Settlement Agreement, FDA Docket Number FDA-2014-H-2281, CRD Docket Number C-15-759.

13. On September 25, 2013, CTP initiated its second CMP action against Respondent, alleging that FDA-commissioned inspectors documented the following violations at Respondent’s establishment:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)) on March 13, 2013, and April 18, 2012; and
- b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1)) on March 13, 2013, and April 18, 2012.

See Compl., FDA Docket Number FDA-2013-H-1115, CRD Docket Number C-13-1308. The CMP Action was closed after Mei Lan Liu d/b/a Yin Hua Lou Restaurant admitted all of the allegations in the Complaint and paid the agreed-upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Attachment to Notice of Settlement Agreement FDA-2013-H-1115, CRD Docket Number C-13-1308.

- 14. On August 7, 2012, CTP initiated its first CMP action against Respondent, alleging that FDA-commissioned inspectors documented the following violations at Respondent's establishment:

- a. Sale to a minor (21 C.F.R. § 1140.14(a)) on April 18, 2012; and
- b. Failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1)) on April 18, 2012.

See Compl., FDA Docket Number FDA-2012-H-0834, CRD Docket Number C-12-1076. The CMP Action was closed after Mei Lan Liu d/b/a Yin Hua Lou Restaurant paid the agreed-upon penalty. See Notice of Settlement Agreement FDA Docket Number FDA-2012-H-0834, CRD Docket Number C-12-1076.

15. As described in the paragraphs above, Respondent has committed:
- a. Three repeated violations and one original violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1); and
 - b. Three repeated violations and one original violation of 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i).

Accordingly, Respondent has committed a total of six repeated violations of particular requirements in 21 C.F.R. Part 1140 within a 36-month period.

OPTIONS FOR RESPONDING TO COMPLAINT

16. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing, unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order. 21 C.F.R. § 17.11. The Answer 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 NTSO, 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.
17. Respondent has the right, but is not required, to retain counsel for representation.

REQUEST FOR RELIEF

18. CTP respectfully requests that this Court impose a no-tobacco-sale order for a period of 30 calendar days on Respondent.

DATED: August 19, 2016

Respectfully submitted,

/s/

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