UNITED STATES OF AMERICA
BEFORE THE ADMINISTRATIVE LAW JUDGE
DEPARTMENTAL APPEALS BOARD
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of:	)	
	)	
Center for Tobacco Products,	)	
	)	
Complainant,	)	
	)	**ADMINISTRATIVE COMPLAINT**
v.	)	**FOR NO-TOBACCO-SALE ORDER**
	)	
Yong Zhu	)	FDA Docket No. FDA-2016-R-2303
d/b/a Foo Kwai Inn,	)	CRD Docket No. T-16-1520
	)	
Respondent.	)	
	)	

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 Yong Zhu, d/b/a Foo Kwai Inn (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.

	Dates of Inspection				
Charged Violation[2]	06/05/2013	12/16/2013 & 12/18/2013	08/11/2014 & 09/05/2014	11/11/2015 & 11/17/2015	**Number of Repeated Violations**
Selling cigarettes / cigarette tobacco / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a)	**OV**	**X**	**X**	**X**	**3**
Failing to verify ID for cigarettes / cigarette tobacco / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1)	**OV**	**X**	**X**	**X**	**3**
FDA Action	Warning Letter Sent 06/27/2013	First CMP Initiated 04/23/2014	Second CMP Initiated 01/26/2015	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 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).

[2] "OV" indicates an original violation. "X"` indicates a repeated violation.

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 Foo Kwai Inn, located at 1724 Bridge Street, Philadelphia, PA 19124.

9. Respondent's establishment receives tobacco products, including Newport Box 100s cigarettes and Newport Kings cigarettes, in interstate commerce and holds them for sale after shipment in interstate commerce.

10. On November 11, 2015**,** an FDA-commissioned inspector conducted an inspection of Foo Kwai Inn and documented that Respondent committed the following violations:

    a. Selling cigarettes, cigarette tobacco, or smokeless tobacco 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 Newport Box 100s cigarettes on November 11, 2015, at approximately 3:10 PM; and

    b. Failing to verify the age of a person purchasing cigarettes, cigarette tobacco, or smokeless tobacco 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 November 11, 2015, at approximately 3:10 PM.

PREVIOUS CASE HISTORY

11. Respondent has been the subject of two prior CTP civil money penalty ("CMP") actions based on its violations of the Act.

12. On January 26, 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 August 11, 2014, December 16, 2013, and June 5, 2013; 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 August 11, 2014, December 16, 2013, and June 5, 2013.

    See Compl., FDA Docket Number FDA-2015-H-0207, CRD Docket Number C-15-1017. The CMP Action concluded with Yong Zhu, d/b/a Foo Kwai Inn admitting all of the allegations in the Complaint and paying the agreed upon penalty, and the Court closing the case. 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-2015-H-0207, CRD Docket Number C-15-1017.

13. On April 23, 2014, 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 December 16, 2013, and June 5, 2013; 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 December 16, 2013, and June 5, 2013.

See Compl., FDA Docket Number FDA-2014-H-0489, CRD Docket Number C-14-979. The CMP Action concluded with Yong Zhu, d/b/a Foo Kwai Inn admitting all of the allegations in the Complaint and paying the agreed upon penalty, and the Court closing the case. 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-0489, CRD Docket Number C-14-979.

14. 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); and

b. Three repeated violations and one original violation of 21 C.F.R. § 1140.14(b)(1).

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

15. 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.

16. Respondent has the right, but is not required, to retain counsel for representation.

REQUEST FOR RELIEF

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

DATED: August 3, 2016

Respectfully submitted,

/s/

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