

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.)
)
Zip Zone Express, Inc.)
d/b/a Zip Zone Express 14,)
)
Respondent.)

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

FDA Docket No. FDA-2017-R-1812
CRD Docket No. T-17-3103

INTRODUCTION

1. The Center for Tobacco Products (“CTP”), Food and Drug Administration (“FDA”), United States Department of Health and Human Services, requests that the Administrative Law Judge (“ALJ”) impose a no-tobacco-sale order (“NTSO”) for a 30 consecutive calendar day period on Zip Zone Express, Inc., d/b/a Zip Zone Express 14 (“Respondent”), for repeatedly violating particular FDA tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (“Act”) (21 U.S.C. § 387f(d)), which are codified in 21 C.F.R. Part 1140. As shown in the following table¹ and described in more detail below, Respondent committed five repeated violations of particular FDA tobacco

¹ As explained in the Previous Case History section of this Complaint, CTP previously filed three civil money penalty (“CMP”) cases against Respondent. The table identifies Respondent’s original violations of FDA’s regulations in 21 C.F.R. Part 1140 and Respondent’s repeated violations of those particular regulations that occurred within a specified 36-month period after the original violations.

regulations within the 36-month period that included February 27, 2014 through August 4, 2016:

Charged Violation ^{2,3}	Violative Inspection Dates					Number of Repeated Violations
	06/06/2013	02/27/2014	10/16/2014	10/26/2015	08/04/2016	
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a) / 21 C.F.R. § 1140.14(a)(1)	OV	X	X	X	X	4
Failing to verify ID for cigarettes / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1) / 21 C.F.R. § 1140.14(a)(2)(i)	OV		X			1
<u>FDA Action</u>	Warning Letter Sent 06/27/2013	First CMP Initiated 09/05/2014 <i>FDA-2014-H-1277, CRD C-14-1803</i>	Second CMP Initiated 03/23/2015 <i>FDA-2015-H-0892, CRD C-15-1721</i>	Third CMP Initiated 04/27/2016 <i>FDA-2016-H-0487, CRD T-16-188</i>	Current Complaint	Total: 5 Repeated Violations

LEGAL AUTHORITY

- The Act provides for an NTSO prohibiting the sale of tobacco products at a retail outlet against any person who commits repeated violations of requirements

² "OV" indicates an original violation. "X" indicates a repeated violation of a particular requirement.

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>, the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained substantively the same. To account for the change in citation form, this chart and complaint will include references to the original and new citations indicated as Original (pre-August 8, 2016) Citation / New (post August 7, 2016) Citation. 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.

promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 21 U.S.C. § 333(f)(8). The regulations at 21 C.F.R. Part 1140 (hereafter, “Part 1140 regulations”) were issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 75 Fed. Reg. 13,225 (Mar. 19, 2010). The term “repeated violations” in 21 U.S.C. § 333(f)(8) is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation.” See Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009).

3. CTP has provided public notice that retailers who have committed five or more repeated violations of particular Part 1140 regulations within a 36-month period may be 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>.

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

CURRENT ALLEGATIONS

5. Respondent owns an establishment which currently does business under the name Zip Zone Express 14 and is located at 3096 16th Street Road, Huntington,

WV 25701. Previously, Fast Lane, Inc., d/b/a Fast Lane, operated at 3096 16th Street Road, Huntington, WV 25701. On September 5, 2014, Fast Lane, Inc. filed with the West Virginia Secretary of State for a name change to Zip Zone Express, Inc. The individuals who were directors and officers for Fast Lane, Inc. at the time of the name change are the current directors and officers for Zip Zone Express, Inc. James Mills, director, treasurer and Vice President of Fast Lane, Inc., signed the acknowledgement form admitting to the violations described in the first CMP, discussed in Paragraph 9 below. James Mills, director, treasurer and Vice President of Zip Zone Express, Inc., signed the acknowledgement form admitting to the violations in the third CMP, discussed in Paragraph 11 below. As noted above, at all times during all violations alleged in this case, there has been an overlap in ownership and management between Fast Lane, Inc., and Zip Zone Express, Inc. Further, the establishment has continued its operations at the same physical location. Although there has been a change in the corporate and d/b/a names of the establishment, there has been continuity of ownership.

6. An FDA-commissioned inspector conducted an inspection at Respondent's establishment on August 4, 2016. During that inspection, Respondent committed a violation of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes on August 4, 2016, at approximately 7:21 PM.
7. On August 8, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on

August 4, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 7:21 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.

PREVIOUS CASE HISTORY

8. Respondent has been the subject of three prior CMP actions based on its violations of the Part 1140 regulations.
9. CTP initiated its first CMP action against Respondent on September 5, 2014, alleging that Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) on June 6, 2013 and February 27, 2014, and failed to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on June 6, 2013. See Compl., FDA Docket Number FDA-2014-H-1277, CRD Docket Number C-14-1803. ("First CMP Action"). The First CMP action was closed after Fast Lane, Inc., d/b/a Fast Lane, 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 First CMP Action, Attachment to Notice of Settlement Agreement.
10. On March 23, 2015, CTP initiated its second CMP action against Respondent, alleging that, in addition to the violations alleged in the First CMP Action,

Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) and failed to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on October 16, 2014. See Compl., FDA Docket Number FDA-2015-H-0892, CRD Docket Number C-15-1721. ("Second CMP Action"). The Second CMP action was closed after Zip Zone Express, Inc., d/b/a Zip Zone Express, 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 Second CMP Action, Attachment to Notice of Settlement Agreement.

11. On April 27, 2016, CTP initiated its third CMP action against Respondent, alleging that, in addition to the violations alleged in the First and Second CMP Actions, Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) on October 26, 2015. See Compl., FDA Docket Number FDA-2016-H-0487, CRD Docket Number T-16-188. ("Third CMP Action"). The Third CMP action was closed after Zip Zone Express, Inc., d/b/a Zip Zone Express, 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 Third CMP Action, Attachment to Notice of Settlement Agreement.

EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO

12. With its most recent sale to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) on August 4, 2016, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on June 6, 2013, in the 36-month period that included February 27, 2014 through August 4, 2016:
 - a. Four repeated violations of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on February 27, 2014, October 16, 2014, October 26, 2015 and August 4, 2016; and
 - b. One repeated violation of failing to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i), on October 16, 2014.

Accordingly, Respondent has committed a total of five repeated violations of particular requirements in 21 C.F.R. Part 1140 within a 36-month period and is subject to an NTSO. See 21 U.S.C. § 333(f)(8).

OPTIONS FOR RESPONDING TO COMPLAINT

13. 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.

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

REQUEST FOR RELIEF

15. CTP respectfully requests that the ALJ impose a no-tobacco-sale order preventing Respondent from selling cigarettes, cigarette tobacco, roll-your own tobacco, smokeless tobacco, and covered tobacco products for a 30 consecutive calendar day period.

DATED: March 23, 2017

Respectfully submitted,

/s/

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