

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.)
)
Guajaca Mini Market Corp)
d/b/a Guajaca Mini Market,)
)
Respondent.)

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

FDA Docket No. FDA-2017-R-1013
CRD Docket No. T-17-2364

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 Guajaca Mini Market Corp, d/b/a Guajaca Mini Market (“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 two 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 June 27, 2015 through April 27, 2016 (hereafter “specified 36-month period”):

Charged Violation ^{2, 3}	Violative Inspection Dates				Number of Repeated Violations
	08/06/2012	02/23/2013	06/27/2015	04/27/2016	
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a) / 21 C.F.R. § 1140.14(a)(1)	OV	NC	X	X	2
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	NC	X	X	2
Selling individual cigarettes, 21 C.F.R. § 1140.14(d) / 21 C.F.R. § 1140.14(a)(4)		OV	X		1
<u>FDA Action</u>	Warning Letter Sent 10/18/2012	First CMP Initiated 05/15/2013 <i>FDA-2013-H-0562, C-13-759</i>	Second CMP Initiated 11/06/2015 <i>FDA-2015-H-3979</i>	Current Complaint	Total: 5 Repeated Violations in 36 months

² “OV” indicates an original violation. “NC” indicates a violation that is not being counted as a repeated violation for purposes of this NTSO case because it falls outside of the 36-month period. “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.

LEGAL AUTHORITY

2. 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 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 that does business under the name Guajaca Mini Market and is located at 724 Springfield Avenue, Irvington, NJ, 07111.
6. An FDA-commissioned inspector conducted an inspection at Respondent's establishment on April 27, 2016. During that inspection, Respondent committed the following violations:
 - a. 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 Newport Box cigarettes April 27, 2016, at approximately 4:46 PM; and
 - b. 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, as required by 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on April 27, 2016, at approximately 4:46 PM.
7. On April 29, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on April 27, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 4:46 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 two prior CMPs based on its violations of the Part 1140 regulations.
9. CTP initiated its first CMP action against Respondent on May 15, 2013, alleging that Respondent sold cigarettes 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 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 August 6, 2012 and February 23, 2013, and sold individual cigarettes (21 C.F.R § 1140.14(d) / 1140.14(a)(4)) on February 23, 2013. See Compl., FDA Docket Number FDA-2013-H-0562, CRD Docket Number C-13-759. ("First CMP Action"). The First CMP action was closed after Guajaca Mini Market Corp, d/b/a Guajaca Mini Market 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.⁴
10. On November 6, 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 to a minor (21 C.F.R. § 1140.14(a)) / 1140.14(a)(1)), failed to verify the age of a person purchasing cigarettes 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)), and sold individual cigarettes (21 C.F.R §

⁴ CTP is not counting the February 23, 2013 violations as "repeated violations" in this NTSO Complaint because they fall outside the specified 36-month period.

1140.14(d) / 1140.14(a)(4)) on June 27, 2015. See Compl., FDA Docket Number FDA-2015-H-3979 (“Second CMP Action”), attached as Exhibit 1. The Second CMP action was dismissed pursuant to settlement after Guajaca Mini Market Corp, d/b/a Guajaca Mini Market 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,⁵ attached as Exhibit 2.

EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO

11. With its most recent sale to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)), and failure to verify identification (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on April 27, 2016, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on August 6, 2012 (sale to minor; failure to verify identification) and February 23, 2013 (sale of individual cigarettes), in the 36-month period that included June 27, 2015 through April 27, 2016:
 - a. Two repeated violations of selling cigarettes to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on June 27, 2015 and April 27, 2016;
 - b. Two repeated violations of failing to verify the age of a person purchasing cigarettes 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 June 27, 2015 and April 27, 2016; and

⁵ CTP is not counting the February 23, 2013 violations as “repeated violations” in this NTSO Complaint because they fall outside the specified 36-month period.

- c. One repeated violation of selling individual cigarettes, in violation of 21 C.F.R. § 1140.14(d) / 1140.14(a)(4), on June 27, 2015.

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

12. 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.
13. Respondent has the right, but is not required, to retain counsel for representation.

REQUEST FOR RELIEF

14. 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: February 16, 2017

Respectfully submitted,

/s/

Wendy S. Vicente

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