

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. )  
 )  
Mendez Fuel Holdings 2 LLC )  
d/b/a Mobil, )  
 )  
Respondent. )  
\_\_\_\_\_

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

FDA Docket No. FDA-2017-R-3548  
CRD Docket No. T-17-4677

**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 day period on Mendez Fuel Holdings 2 LLC, d/b/a Mobil (“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 table<sup>1</sup> and described in more detail below, Respondent

---

<sup>1</sup> 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.

committed five repeated violations of particular FDA tobacco regulations within the 36-month period that included September 23, 2015 to January 11, 2017:

Charged Violation <sup>2,3</sup>	Violative Inspection Dates				Number of Repeated Violations
	03/19/2015	09/23/2015	03/09/2016	01/11/2017	
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	3
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		X	2
<b>FDA Action</b>	Warning Letter Sent 04/30/2015	First CMP Initiated 01/15/2016 FDA-2015-H-4918	Second CMP Initiated 09/27/2016 FDA-2016-H-2877 CRD T-16-2064	Current Inspection	<b>Total: 5 Repeated Violations</b>

### **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 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

<sup>2</sup> “OV” indicates an original violation. “X” indicates a repeated violation of a particular requirement.

<sup>3</sup> 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.

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:

<b>Number of NTSOs received by Retailer</b>	<b>Maximum Period of Time for NTSO</b>
First NTSO	30 Consecutive 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 Mobil and is located at 701 Northwest 72nd Avenue, Miami, FL 33126.
6. An FDA-commissioned inspector conducted an inspection at Respondent’s establishment on January 11, 2017. 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 on January 11, 2017, at approximately 8:51 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 January 11, 2017, at approximately 8:51 PM.
7. On January 18, 2017, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on January 11, 2017, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 8:51 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 CMP actions based on its violations of the Part 1140 regulations.
9. CTP initiated its first CMP action against Respondent on January 15, 2016, alleging that 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 March 19, 2015 and September 23, 2015. See Compl., FDA Docket Number FDA-2015-H-4918 ("First CMP Action"), attached at Exhibit 1. The First CMP action was dismissed pursuant to settlement after Mendez Fuel Holdings 2 LLC, d/b/a Mobil 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, attached at Exhibit 2.

10. On September 27, 2016, 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)) on March 9, 2016. See Compl., FDA Docket Number FDA-2016-H-2877, CRD Docket Number T-16-2064. ("Second CMP Action"). The Second CMP action was closed after Mendez Fuel Holdings 2 LLC, d/b/a Mobil 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.

## **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 January 11, 2017, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on March 19, 2015, in the 36-month period that included September 23, 2015 to January 11, 2017:
- a. Three 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 September 23, 2015, March 9, 2016, and January 11, 2017; and
  - b. Two repeated violations 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 September 23, 2015 and January 11, 2017.

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 day period.

DATED: June 5, 2017

Respectfully submitted,

/s/

**James C. Fraser**

Attorney for Complainant

Center for Tobacco Products

United States Food and Drug  
Administration

White Oak 31, Room 4531A

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Telephone: (240) 402-2638

Fax: (301) 847-8637

Email: [james.fraser@fda.hhs.gov](mailto:james.fraser@fda.hhs.gov)