

UNITED STATES OF AMERICA  
BEFORE THE DEPARTMENTAL APPEALS BOARD  
CIVIL REMEDIES DIVISION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Case of: )  
 )  
Center for Tobacco Products, )  
 )  
Complainant, )  
 )  
v. )  
 )  
God Is One Petroleum Inc. )  
d/b/a Keystone Food Mart, )  
 )  
Respondent. )  
\_\_\_\_\_

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

FDA Docket No. FDA-2017-R-2800  
CRD Docket No. T-17-3987

**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 God Is One Petroleum Inc., d/b/a Keystone Food Mart (“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,

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<sup>1</sup> 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.

Respondent committed five repeated violations of particular FDA tobacco regulations within the 36-month period that included 02/08/2015 to 12/21/2016:

Charged Violation <sup>2,3</sup>	Violative Inspection Dates					Number of Repeated Violations
	01/15/2014	06/06/2014	02/08/2015	10/06/2015	12/21/2016	
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	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
Having a self-service display in a facility not restricted to 18+, 21 C.F.R. § 1140.16(c)	OV					
<b><u>FDA Action</u></b>	Warning Letter Sent 03/06/2014	First CMP Initiated 12/03/2014 FDA-2014-H-2040 CRD C-15-545	Second CMP Initiated 06/08/2015 FDA-2015-H-1927 CRD C-15-2694	Third CMP Initiated 01/26/2016 FDA-2016-H-0068	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.

<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.

§ 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:

<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 Keystone Food Mart and is located at 3950 South Keystone Avenue, Indianapolis, IN 46227.

6. An FDA-commissioned inspector conducted an inspection at Respondent's establishment on December 21, 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 Newport Box cigarettes on December 21, 2016, at approximately 8:09 PM.
7. On December 28, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on December 21, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 8:09 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 December 3, 2014, 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 June 6, 2014 and February 8, 2015. See Compl., FDA

Docket Number FDA-2014-H-2040, CRD Docket Number C-15-545. (“First CMP Action”). The First CMP action was closed after God Is One Petroleum Inc. / Kamaljit Kaur, d/b/a Keystone Food Mart 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 June 8, 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 February 8, 2015. See Compl., FDA Docket Number FDA-2015-H-1927, CRD Docket Number C-15-2694. (“Second CMP Action”). The Second CMP action was closed after God Is One Petroleum Inc., d/b/a Keystone Food Mart 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 January 26, 2016, CTP initiated its third 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 6, 2015. See Compl., FDA Docket Number FDA-2016-H-0068. ("Third CMP Action"), attached at Exhibit 1. The Third CMP action was closed pursuant to settlement after God Is One Petroleum Inc., d/b/a Keystone Food Mart 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, attached at Exhibit 2.

**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 December 21, 2016, see paragraph 6 of this Complaint, Respondent committed the following five repeated violations of regulations that it originally violated on June 6, 2014, in the 36-month period that included February 8, 2015 to December 21, 2016:
  - 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 February 8, 2015, October 6, 2015, and December 21, 2016; 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 February 8, 2015 and October 6, 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**

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 day period.

DATED: **May 4, 2017**

Respectfully submitted,

*/s/*

**Joshua Davenport**

Attorney for Complainant  
Center for Tobacco Products  
United States Food and Drug Administration  
White Oak 31, Room 4586  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Telephone: (301) 796-6717  
Fax: (301) 847-8638  
Email: [joshua.davenport@fda.hhs.gov](mailto:joshua.davenport@fda.hhs.gov)