

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.)
)
Saab Petro Mart Inc.)
d/b/a BP,)
)
Respondent.)

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

FDA Docket No. FDA-2016-R-2028
CRD Docket No. T-16-1286

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 Saab Petro Mart Inc., d/b/a BP (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.

Charged Violation²	Dates of Inspection				Number of Repeated Violations
	10/26/2013	03/08/2014 & 03/28/2014	01/03/2015 & 01/07/2015	08/26/2015 & 09/02/2015	
Sale of cigarettes / cigarette tobacco / smokeless tobacco to a minor. 21 C.F.R. § 1140.14(a)	OV	X	X	X	3
Failure to verify ID for cigarettes / cigarette tobacco / smokeless tobacco sale. 21 C.F.R. § 1140.14(b)(1)	OV	X	X	X	3
<u>FDA Action</u>	Warning Letter Sent 01/09/2014	First CMP Initiated 09/15/2014	Second CMP Initiated 05/20/2015	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 BP, located at 8406 Linwood Street, Detroit, MI 48206.
9. Respondent's establishment receives tobacco products, including Newport Box 100s cigarettes, in interstate commerce and holds them for sale after shipment in interstate commerce.
10. On August 26, 2015, an FDA-commissioned inspector conducted an inspection of Saab Petro Mart Inc., d/b/a BP and documented that the 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 August 26, 2015, at approximately 11:10 AM; 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 August 26, 2015, at approximately 11:10 AM.

PREVIOUS CASE HISTORY

11. The Respondent has been the subject of two prior CTP Civil Money Penalty ("CMP") actions based on its violations of the Act.

12. On May 20, 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 January 3, 2015, March 8, 2014, and October 26, 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 January 3, 2015, March 8, 2014, and October 26, 2013.See Compl., FDA Docket Number FDA -2015-H-1621, CRD Docket Number C-15-2431. The CMP Action concluded with Saab Petro Mart Inc. d/b/a BP 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-1621, CRD Docket Number C-15-22431.
13. On September 15, 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 March 8, 2014, and October 26, 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 March 8, 2014, and October 26, 2013.

See Compl., FDA Docket Number FDA -2014-H-1337, CRD Docket Number C-14-1852. The CMP Action concluded with Saab Petro Mart Inc. d/b/a BP 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-1337, CRD Docket Number C-14-1852.

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 imposing the proposed civil money penalty. 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 CMP, 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: July 13, 2016

Respectfully submitted,

/s/

Nathan Sabel
Attorney for Complainant
Center for Tobacco Products
United States Food and Drug
Administration
White Oak 31, Room 4522
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
Telephone: (301) 796-8620
Fax: (301) 847-8638
Email: Nathan.Sabel@fda.hhs.gov