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. QM Enterprises, Inc. d/b/a BP, Respondent.	**ADMINISTRATIVE COMPLAINT FOR NO-TOBACCO-SALE ORDER** FDA Docket No. FDA-2016-R-2885 CRD Docket No. T-16-2070

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 QM Enterprises, 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 five 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.

	Violative Inspection Dates				
Charged Violation[2, 3]	02/24/2013	07/20/2013	06/06/2014	11/28/2015	**Number of Repeated Violations**
Selling cigarettes / cigarette tobacco / 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 / cigarette tobacco / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1) / 21 C.F.R. § 1140.14(a)(2)(i)	**OV**		**X**	**X**	**2**
FDA Action	Warning Letter Sent 03/14/2013	First CMP Initiated 02/04/2014 FDA-2014-H-0097 CRD C-14-565	Second CMP Initiated 01/09/2015 FDA-2014-H-2312 CRD C-15-800	Current Complaint	**Total: 5 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

[2] "OV" indicates an original violation. "X"` indicates a repeated violation.

[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 (hereafter, "Deeming Regulation"), the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained the same. The chart includes references to the original and new citations; 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.

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).

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 and is located at 714 East Warren Avenue, Detroit, MI 48201.

9. Respondent's establishment receives tobacco products in interstate commerce, including Newport Box cigarettes and Newport Box 100s cigarettes, and holds them for sale after shipment in interstate commerce.

10. On November 28, 2015, an FDA-commissioned inspector conducted an inspection of BP. During that inspection, Respondent committed the following violations:

    a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on November 28, 2015, at approximately 10:43 AM; and

    b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on November 28, 2015, at approximately 10:43 AM.

PREVIOUS CASE HISTORY

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

12. On January 9, 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 December 17, 2014, July 26, 2013, and February 24, 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 December 17, 2014, and February 24, 2013.

    See Compl., FDA Docket Number FDA-2014-H-2312, CRD Docket Number C-15-800. The CMP Action was closed after a final default judgment against QM Enterprises, Inc. d/b/a BP, finding that all of the violations alleged in the Complaint occurred. See Initial Decision and Default Judgment, FDA-2014-H-2312, CRD Docket Number C-15-800, CRD Decision No. CR3687.

13. On February 4, 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 July 26, 2013, and February 24, 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 February 24, 2013.

See Compl., FDA Docket Number FDA-2014-H-0097, CRD Docket Number C-14-565. The CMP Action was closed after QM Enterprises, Inc. d/b/a BP 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 Attachment to Notice of Settlement Agreement FDA-2014-H-0097, CRD Docket Number C-14-565.

14. As described in the paragraphs above, Respondent has committed:

a. Three repeated violations and one original violation of sale to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1); and

b. Two repeated violations and one original violation of failure to verify the age of a person purchasing tobacco products 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).

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.

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. 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.

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: September 23, 2016

Respectfully submitted,

/s/

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