UNITED STATES OF AMERICA
BEFORE THE ADMINISTRATIVE LAW JUDGE
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of: Center for Tobacco Products, Complainant, v. MFA Petroleum Company d/b/a Break Time 3028, Respondent.	**ADMINISTRATIVE COMPLAINT FOR NO-TOBACCO-SALE ORDER** FDA Docket No. FDA-2015-R-3483

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 MFA Petroleum Company, d/b/a Break Time 3028 (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 violations of regulations promulgated under Section 906(d) of the Act, 21 U.S.C. § 387f(d), but excludes repeated violations that occurred outside of the 36-month period or any violations of other sections of the Act for which Respondent may be liable.

	Dates of Inspection				
Charged Violation	08/07/2013	01/21/2014 & 01/23/2014	12/13/2014 & 12/17/2014	06/08/2015 & 06/10/2015	**Number of Repeated Violations**
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a)	OV[2]	X	X	X	**3**
Failing to verify ID for cigarettes / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1)	OV	X		X	**2**
FDA Action	Warning Letter Sent 09/19/2013	First CMP Initiated 06/20/2014	Second CMP Initiated 04/08/2015	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 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. FDA has documented multiple repeated violations of 21 C.F.R. Part 1140 at Respondent's establishment, as detailed below.

7. 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.

CURRENT ALLEGATIONS

8. Respondent owns an establishment that does business under the name Break Time 3028, located at 110A East Nifong Boulevard, Columbia, MO 65203.

9. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

10. Most recently during a two-part inspection of Respondent's establishment conducted on June 8 and 10, 2015, FDA-commissioned inspectors documented the following violations:

    a. Selling 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 Grizzly Long Cut Premium Wintergreen smokeless tobacco on June 8, 2015, at approximately 10:59 AM; and

    b. Failing to verify the age of a person purchasing 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 detailed above, on June 8, 2015, at approximately 10:59 AM.

PREVIOUS CASE HISTORY

11. Previously, on April 8, 2015, CTP initiated a CMP action 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 13, 2014, January 21, 2014, and August 7, 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 21, 2014, and August 7, 2013.

See Compl., FDA Docket Number FDA-2015-H-1098, CRD Docket Number C-15-1929 (Most Recent CMP Action); *see also* FDA Docket Number FDA-2014-H-0808, CRD Docket Number C-14-1315.

12. The Most Recent CMP Action concluded with MFA Petroleum Company d/b/a Break Time 3028 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-1098, CRD Docket Number C-15-1929.

13. 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. Two repeated violations and one original violation of 21 C.F.R. § 1140.14(b)(1).

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

14. Respondent must take one of the following actions within the time listed below:

a. Contact CTP to Discuss Options: If Respondent wishes to resolve this case without a hearing, Respondent may contact CTP to discuss the terms of the proposed NTSO within 15 days after service of the Complaint. Respondent is still responsible for meeting all deadlines associated with the case until the case is closed. If an agreement between the parties is not reached within 30 days after service of the Complaint, Respondent must submit an Answer, *see* Option b, or be granted an extension of time to file the Answer, *see* Option c. CTP's contact information is provided in the cover letter that accompanies this Complaint.

b. File an Answer: Respondent has the right to request a hearing by filing an Answer. The Answer shall be deemed to be a request for a hearing, unless the Answer states otherwise. The Answer must be filed within 30 days after service of the Complaint or the Administrative Law Judge may impose the proposed NTSO. 21 C.F.R. § 17.11. Instructions for filing the Answer are set forth in paragraphs 17 and 18.

c. Request an Extension: Respondent has the right to request an extension of up to 30 additional days to file an Answer, if good cause exists for Respondent's inability to respond timely. This request must be made within 30 days after service of the Complaint. A request for an extension is not automatically granted. Instructions for filing for an extension are set forth in paragraphs 22 and 23.

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

INSTRUCTIONS FOR FILING AN ANSWER TO REQUEST A HEARING

16. Rules for drafting and filing the Answer are found at 21 C.F.R. § 17.9.

17. If filing an Answer:

a. The Answer must include the following:

i. Admission or denial of each of the allegations of liability found in this Complaint, including specifically the allegations in paragraphs 8 through 10. Allegations not specifically denied in the Answer will be considered admitted;

ii. All defenses on which Respondent intends to rely;

iii. Information (if any) regarding steps Respondent has taken to prevent future violations;

iv. All reasons (if any) why Respondent contends that the proposed time period for the NTSO should be less than the amount stated in paragraph 25; and

v. The name, address, and telephone number of Respondent's counsel (if any). Other contact information, such as email address, may be included.

b. The Answer may also include a request for an informal Settlement Conference to discuss reducing the proposed time period for the NTSO. Such a request may be filed as a part of the Answer, but is not an alternative to filing a complete Answer. If an informal Settlement

Conference results in an agreement between the parties, a hearing may no longer be necessary.

18. The Answer may be filed with FDA's Division of Dockets by email at FDA-ALJ-Dockets@FDA.HHS.GOV or by mail by sending it to: Division of Dockets Management, Food and Drug Administration, Attn: FDA ALJ Dockets, 10903 New Hampshire Avenue, WO1 – 1310, Silver Spring, MD 20993-0002. A sample Answer is included in the Cover Letter. If emailing an Answer, Respondent should reference the FDA docket number (found at the top of this document and in the Cover Letter) in the email's subject line. In addition to the Answer, each party's representative must provide a signed notice of appearance or statement that s/he is authorized to act on the party's behalf.

19. If Respondent needs to amend its Answer after it has been filed, Respondent may file a motion to amend with the Court using the filing methods discussed in paragraph 18. The motion must include the FDA docket number and if filing by email, Respondent should reference the FDA docket number in the email's subject line.

20. After Respondent files its Answer, the Court will notify Respondent regarding the details of the hearing and/or the hearing process. This information may include a requirement by the ALJ to attend a settlement conference before going to hearing. Respondent may settle with CTP prior to any Court-required settlement conference or during a Court settlement conference.

21. The failure to file an Answer or otherwise resolve this matter with CTP within 30 days after service of the Complaint may result in the imposition of the proposed NTSO. 21 C.F.R. § 17.11.

INSTRUCTIONS FOR FILING A REQUEST FOR AN EXTENSION

22. Within 30 days after service of the Complaint, Respondent may request an extension of time to file an Answer. 21 C.F.R. § 17.9(c). The request should include an explanation of why there is good cause for Respondent to be given additional time to prepare an Answer in writing. Respondent should continue to prepare its Answer because, if the extension is denied, the initial 30-day timeframe is all the time provided to respond to this Complaint.

23. The request for an extension should be filed using the filing methods discussed in paragraph 18. The request must include the FDA docket number. If filing by email, Respondent should reference the FDA docket number in the email's subject line.

24. The ALJ may grant Respondent up to 30 additional days to file an Answer, if good cause is shown. 21 C.F.R. § 17.9(c).

REQUEST FOR RELIEF

25. CTP respectfully requests that this Court impose a no-tobacco-sale order for a period of 30 calendar days on Respondent.

DATED: October 26, 2015

Respectfully submitted,

/s/

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