

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1248)

Complainant

v.

Orange Petromart L.L.C.
d/b/a Orange Petromart / Mobil Mart,

Respondent.

Docket No. C-14-1767

Decision No. CR3459

Date: November 13, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Orange Petromart L.L.C. d/b/a Orange Petromart / Mobil Mart, at 248 Boston Post Road, Orange, Connecticut 06477, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Orange Petromart / Mobil Mart impermissibly sold cigarettes to a minor, utilized a self-service display in a non-exempt facility, and failed to verify, by means of photo identification containing a date of birth, that a cigarette purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Orange Petromart / Mobil Mart previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$10,000 civil money penalty against Respondent Orange Petromart / Mobil Mart.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 15, 2014, CTP served the complaint on Respondent Orange Petromart / Mobil Mart by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent Orange Petromart / Mobil Mart has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to Respondent Orange Petromart / Mobil Mart on November 15, 2012, citing violations¹ of 21 C.F.R. pt. 1140 on September 27, 2012, at Respondent's business establishment, 248 Boston Post Road, Orange, Connecticut 06477;
- On August 21, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1118, FDA Docket Number FDA-2013-H-0921, against Respondent for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred on September 27, 2012, and February 20, 2013;
- The previous action concluded when Tahir Mahmood, Respondent's authorized representative, settled the claims on Respondent's behalf. On October 10, 2013, Mr. Mahmood signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on November 25, 2013;

¹ In the complaint, CTP describes the actions that took place at Respondent Orange Petromart L.L.C. d/b/a Orange Petromart's business establishment on September 27, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint initiated on August 21, 2013, and attached to the present complaint, CTP described two discrete violations at Orange Petromart L.L.C. d/b/a Orange Petromart / Mobil Mart's business establishment on September 27, 2012: a violation of 21 C.F.R. § 1140.14(a) and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on September 27, 2012, was a typographical error.

- During a two-part inspection on December 11, 2013 and December 23, 2013, FDA-commissioned inspectors documented the following at Respondent's business establishment: Respondent's staff sold cigarettes to a minor and failed to verify the minor's identification before the sale on December 11, 2013 at 4:59 PM; and the presence of a customer-accessible shelf of cigarettes on December 23, 2013.

These facts establish Respondent Orange Petromart / Mobil Mart's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no smokeless tobacco purchasers are younger than 18 years of age. The regulations also require a retailer to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine). 21 C.F.R. § 1140.14(c).

Under 21 C.F.R. § 17.2, a \$10,000 civil money penalty is permissible for six violations of the regulations found at 21 C.F.R. pt. 1140 within a forty-eight month period.

Order

For these reasons, I enter default judgment in the amount of \$10,000 against Respondent Orange Petromart L.L.C. d/b/a Orange Petromart / Mobil Mart. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge