

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-0882)

Complainant

v.

8 Mile and Gratiot, Inc. / Salah Jaern d/b/a Gulf,

Respondent.

Docket No. C-14-1385

Decision No. CR3348

Date: August 28, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, 8 Mile and Gratiot, Inc. / Salah Jaern d/b/a Gulf, at 15000 East 8 Mile Road, Detroit, Michigan 48205, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Gulf unlawfully sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that cigarette purchasers were 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. CTP seeks to impose a \$500 civil money penalty against Respondent Gulf.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 1, 2014, CTP served the complaint on Respondent Gulf 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 Gulf 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:

- At Respondent's business establishment, 15000 East 8 Mile Road, Detroit, Michigan 48205, on June 20, 2013, at approximately 10:15 AM, an FDA-commissioned inspector observed Respondent's staff sell a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspector also noted that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older;
- In a warning letter issued on July 18, 2013, CTP informed Respondent of the inspector's observations from June 20, 2013, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that if Respondent failed to correct its violations, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 15000 East 8 Mile Road, Detroit, Michigan 48205, on November 21, 2013, at approximately 5:07 PM, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspectors also noted that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older.

These facts establish Respondent'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 cigarettes or 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 photo identification containing the bearer's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age.

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent 8 Mile and Gratiot, Inc. / Salah Jaern d/b/a Gulf. 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