

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1595)

Complainant

v.

Zaref, Inc.
d/b/a Sunoco,

Respondent.

Docket No. C-15-98

Decision No. CR3523

Date: December 22, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Zaref, Inc. d/b/a Sunoco, at 942 Middlebelt Road, Inkster, Michigan 48141, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Sunoco impermissibly sold cigarettes to a minor, and failed to verify by means of photo identification containing a date of birth, that a tobacco 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 Sunoco previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent Sunoco.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 21, 2014, CTP served the complaint on Respondent Sunoco 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 Sunoco 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 Sunoco on January 3, 2013, citing violations¹ of 21 C.F.R. pt. 1140 on December 4, 2012, at Respondent's business establishment, 942 Middlebelt Road, Inkster, Michigan 48141;
- On November 26, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-260, FDA Docket Number FDA-2013-H-1452, 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 December 4, 2012, and June 1, 2013;
- The previous action concluded when Mohammad Adoure, Respondent's authorized representative, settled the claims on Respondent's behalf. On December 30, 2013, Mr. Adoure 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 January 24, 2014;
- At approximately 9:39 AM on April 12, 2014, at Respondent's business establishment, 942 Middlebelt Road, Inkster, Michigan 48141, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age.

¹ In the complaint, CTP describes the action or actions that took place at Respondent Sunoco's business establishment on December 4, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint issued on November 26, 2013, and attached to the present complaint, CTP described two discrete violations at Respondent's business establishment on December 4, 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 December 4, 2012, was a typographical error.

The inspectors also documented that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the purchaser of a tobacco product was 18 years of age or older.

These facts establish Respondent Sunoco'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 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.

Under 21 C.F.R. § 17.2, a \$5,000 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,000 against Respondent Zaref, Inc. d/b/a Sunoco. 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