

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-0911)

Complainant

v.

Monroe Stop Shop, Inc.
d/b/a Valero,

Respondent.

Docket No. C-14-1405

Decision No. CR3364

Date: September 11, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Monroe Stop Shop, Inc. d/b/a Valero, at 3080 North Monroe Street, Monroe, Michigan 48162, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Valero impermissibly sold cigarettes to a minor, 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 Valero previously admitted to two violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$500 civil money penalty against Respondent Valero.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 17, 2014, CTP served the complaint on Respondent Valero 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 Valero 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 Valero on September 20, 2012, citing violations¹ of 21 C.F.R. pt. 1140 on July 13, 2012, at Respondent's business establishment, 3080 North Monroe Street, Monroe, Michigan 48162;
- On August 20, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1150, FDA Docket Number FDA-2013-H-0941, against Respondent for two violations of 21 C.F.R. pt. 1140 within a twelve-month period. CTP alleged those violations to have occurred on July 13, 2012, and February 21, 2013;
- The previous action concluded when Ali Elsayed, Respondent's authorized representative, settled the claims on Respondent's behalf. On September 4, 2013, Mr. Elsayed 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 October 3, 2013;
- At approximately 10:19 a.m. on November 10, 2013, at Respondent's business establishment, 3080 North Monroe Street, Monroe, Michigan 48162, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 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 Valero's business establishment on July 13, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint issued on August 9, 2013, and attached to the present complaint, CTP described two discrete violations at Respondent Valero's business establishment on July 13, 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 July 13, 2012, was a typographical error.

These facts establish Respondent Valero'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. § 17.2, a \$500 civil money penalty is permissible for three violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Monroe Stop Shop, Inc. d/b/a Valero. 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