Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1321)

Complainant,

v.

Perry Sunoco Inc. d/b/a Sunoco,

Respondent.

Docket No. C-14-1828

Decision No. CR3448

Date: November 10, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Perry Sunoco Inc., d/b/a Sunoco, at 1144 North Perry Street, Pontiac, Michigan 48340 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 unlawfully sold cigarettes to minors, 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. CTP seeks to impose a \$500 civil money penalty against Respondent Sunoco.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 10, 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:

- At approximately 5:33 p.m. on April 26, 2013, at Respondent's business establishment, at 1144 North Perry Street, Pontiac, Michigan 48340, an FDA-commissioned inspector observed a person younger than 18 years of age enter the establishment and purchase a package of Newport Box 100s cigarettes;
- In a warning letter dated May 9, 2013, CTP informed Respondent of the inspector's April 26, 2013 observation, and that such actions violate federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 12:31 p.m. on March 8, 2014, at Respondent's business establishment, at 1144 North Perry Street, Pontiac, Michigan 48340, FDA-commissioned inspectors observed a person younger than 18 years of age enter the establishment and purchase a package of Newport Box 100s cigarettes. The inspectors also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser 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 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 photographic identification containing a purchaser's date of birth, that no cigarette purchasers are 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 Perry Sunoco 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.

Catherine Ravinski Administrative Law Judge