Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1333)

Complainant,

v.

Singh Convenience Plus Inc. d/b/a Sunoco,

Respondent.

Docket No. C-14-1848

Decision No. CR3462

Date: November 14, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Singh Convenience Plus Inc. d/b/a Sunoco, at 60 South Main Street, Winsted, Connecticut 06098 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 utilized a self-service display of cigarette tobacco in a non-exempt facility, sold cigarettes to a minor, 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 16, 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 Respondent's business establishment, 60 South Main Street, Winsted, Connecticut 06098, on October 25, 2013, at an undisclosed time, an FDA-commissioned inspector observed the presence of a self-service display of cigarette tobacco. The inspector also observed that the establishment was open to the general public during business hours;
- In a warning letter issued on December 26, 2013, CTP informed Respondent of the inspector's observations from October 25, 2013, and that such an action violates federal law, 21 C.F.R. § 1140.16(c). The letter further warned that if Respondent failed to correct its violation, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 60 South Main Street, Winsted, Connecticut 06098, on March 10, 2014, at approximately 3:20 PM, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro Silver Pack 100's cigarettes to a person younger than 18 years of age. 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'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. 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. § 1140.16(c).

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 Singh Convenience Plus 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.

Catherine Ravinski Administrative Law Judge