Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2013-H-0679)

Complainant

v.

SRSM LLC d/b/a Sam's Food Stores,

Respondent.

Docket No. C-13-866

Decision No. CR2889

Date: August 12, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, SRSM LLC d/b/a Sam's Food Stores, at 259 West Washington Street, Bristol, Connecticut 06010, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Sam's Food Stores impermissibly sold cigarettes to a minor, failed to verify the purchaser's age by means of photo identification containing a date of birth and utilized a self-service display in a non-exempt facility, violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose a \$250 civil money penalty against Respondent Sam's Food Stores.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on June 12, 2013, CTP served the complaint on Respondent Sam's Food Stores by United Parcel Service. For reasons entirely unexplained, CTP failed to file proof of service with the Civil

Remedies Division until August 8, 2013, nearly two months after it served Respondent Sam's Food Stores. It was only after I issued a Notice of Intent to Dismiss CTP's case that CTP submitted proof of service. Nevertheless, 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 Sam's Food Stores 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, 259 West Washington Street, Bristol, Connecticut 06010, on July 11, 2012, an FDA-commissioned inspector observed a sale of Parliament Full Flavor cigarettes to a person younger than 18 years of age;
- At Respondent's business establishment, 259 West Washington Street, Bristol, Connecticut 06010, on July 11, 2012, an FDA-commissioned inspector observed that staff failed to verify, by means of photo identification containing the bearer's date of birth, that the purchaser of the Parliament Full Flavor cigarettes was 18 years of age or older;
- In a warning letter dated September 20, 2012, CTP informed Respondent of the inspector's July 11, 2012 observations, and that such actions violate federal law, 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- During a two-part inspection conducted on January 2, 2013, and January 16, 2013, at Respondent's business establishment, 259 West Washington Street, Bristol, Connecticut 06010, FDA commissioned inspectors documented the presence of a self-service display of cigarette tobacco products. The inspectors also documented that the establishment is open to the public and Respondent does not prohibit persons younger than 18 years of age from entering.

These facts establish that Respondent Sam's Food Stores is liable 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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); see 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 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), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. Under 21 C.F.R. § 1140.16(c), retailers are prohibited from using self-service displays to sell cigarettes or smokeless tobacco, unless the facility is one in which persons younger than 18 years of age are not permitted to enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent SRSM LLC d/b/a Sam's Food Stores. 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/
Carolyn Cozad Hughes
Administrative Law Judge