Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1214)

Complainant,

v.

Oak Grove Liquors, Inc.,

Respondent.

Docket No. C-14-1730

Decision No. CR3429

Date: October 24, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Oak Grove Liquors, Inc., at 300 Holly Drive, Middle River, Maryland 21220, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Oak Grove Liquors, Inc. unlawfully sold cigarettes to minors, 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 \$250 civil money penalty against Respondent Oak Grove Liquors, Inc.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 25, 2014, CTP served the complaint on Respondent Oak Grove Liquors, Inc. 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 Oak Grove Liquors, Inc. 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, 300 Holly Drive, Middle River, Maryland 21220, on September 12, 2013, at approximately 4:14 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Newport Box cigarettes to a person younger than 18 years of age;
- In a warning letter issued on November 7, 2013, CTP informed Respondent of the inspector's observation from September 12, 2013, and that such an action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that if Respondent failed to correct its violations, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 300 Holly Drive, Middle River, Maryland 21220, on February 19, 2014, at approximately 12:14 PM, FDAcommissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age.

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.

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 Oak Grove Liquors, Inc. 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