Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-1456)

Complainant,

v.

Mini Rite Grocery LLC d/b/a Mini-Rite Market.

Respondent.

Docket No. C-14-1980

Decision No. CR3487

Date: December 1, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Mini Rite Grocery LLC d/b/a Mini-Rite Market, at 460 Bird Street, Bridgeport, Connecticut 06605, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Mini Rite Grocery impermissibly sold cigarettes to a minor, failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, and opened packages of cigarettes in order to sell individual cigarettes, 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 Mini Rite Grocery.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 2, 2014, CTP served the complaint on Respondent Mini Rite Grocery 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 Mini Rite Grocery 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 1:27 p.m. on October 21, 2013, at Respondent's business establishment, 460 Bird Street, Bridgeport, Connecticut 06605, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspector also observed 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;
- In a warning letter issued January 2, 2014, CTP informed Respondent of the inspector's October 21, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (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;
- Subsequently, during a two-part inspection conducted on March 17 and April 2, 2014, at Respondent's business establishment, 460 Bird Street, Bridgeport, Connecticut 06605, FDA-commissioned inspectors documented the presence of individual unpackaged cigarettes. Respondent's staff confirmed that the cigarettes were available for individual purchase.

These facts establish Respondent Mini Rite Grocery'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 § 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 § 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. § 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.

Moreover, 21 C.F.R. § 1140.14(d) dictates that no retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes.

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 Mini Rite Grocery LLC d/b/a Mini-Rite Market. 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