Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-2041)

Complainant

v.

Kiran Mart LLC,

Respondent.

Docket No. C-15-546

Decision No. CR3609

Date: January 30, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Kiran Mart LLC, at 1450 Southford Road, Southbury, Connecticut 06488, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Kiran Mart used a self-service display 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 Kiran Mart.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 4, 2014, CTP served the complaint on Respondent Kiran Mart 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 Kiran Mart 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:

- On April 19, 2013, at Respondent's business establishment, 1450 Southford Road, Southbury, Connecticut 06488, an FDA-commissioned inspector observed cigarettes for sale from both the main sales floor and a customer-accessible humidor. The inspector further observed that the establishment was open to the public during regular business hours;
- In a warning letter dated August 1, 2013, CTP informed Respondent of the inspector's April 19, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.16(c). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 11:23 a.m. on May 30, 2014, at Respondent's business establishment, 1450 Southford Road, Southbury, Connecticut 06488, FDA-commissioned inspectors documented Respondent's staff selling a package of Pall Mall Menthol cigarettes to a person younger than 18 years of age. 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 Kiran Mart'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 tobacco products 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 purchasers of tobacco products are younger than 18 years of age.

A self-service display is a method of sale expressly prohibited by the regulations unless the self-service display is located in a facility in which the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. \$ 1140.16(c)(2)(ii).

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 Kiran Mart LLC. 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