Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Sliderz Bar & Grille, Inc.,

Respondent.

Docket No. C-14-271 FDA Docket No. FDA-2013-H-1470

Decision No. CR3101

Date: February 3, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Sliderz Bar & Grille, Inc., alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not timely answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and order that Respondent pay a civil money penalty in the amount of \$2,000.

CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent utilized a vending machine to sell regulated tobacco products in a non-exempt facility, impermissibly sold cigarettes to minors and failed to verify that cigarette purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000.

On December 4, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. 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 within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Sliderz Bar & Grille, an establishment that sells tobacco products and is located at 5995 East U.S. Route 36, Decatur, Illinois 62521. Complaint ¶ 3.
- On February 5, 2013, during an inspection of Sliderz Bar & Grille, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes from a vending machine in Respondent's establishment . . . at approximately 6:13 PM CT . . . [and] the minor's identification was not verified before the sale" Complaint ¶ 10.
- On February 21, 2013, CTP issued a Warning Letter to Sliderz Bar & Grille explaining that the inspector's February 5, 2013 observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a), (b)(1), and (c). In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.
- United Parcel Service records indicate that an individual named "Gren" received the Warning Letter on February 22, 2013, but the FDA did not receive a response from Respondent. Complaint ¶ 11.

• On June 4, 2013, during a subsequent inspection of Respondent's establishment, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro Menthol Gold Pack cigarettes from a vending machine in Respondent's establishment . . . at approximately 11:36 AM . . . [and] the minor's identification was not verified before the sale" Complaint ¶ 1.

These facts establish that Respondent 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. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). Under 21 C.F.R. § 1140.14(a), retailers may not sell cigarettes 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 cigarette purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.14(c), a retailer may sell cigarettes only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device, such as a vending machine. However, vending machines containing cigarettes are permitted in facilities where 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).

Here, on February 5, 2013, and June 4, 2013, Respondent violated 21 C.F.R. § 1140.14(c) by utilizing a vending machine to sell cigarettes in a facility that permitted persons younger than 18 years of age to enter. On both of those dates, a minor was able to enter the establishment and purchase a package of cigarettes from the vending machine, in violation of 21 C.F.R. § 1140.14(a), and Respondent's staff did not verify, by checking the cigarette purchaser's photographic identification, that the cigarette purchaser was 18 years of age or older prior to the sale, in violation of 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions and omissions on two separate occasions at the same retail outlet constitute violations of law that warrant a civil money penalty. Accordingly, I find that a civil money penalty of \$2,000 is permissible under 21 C.F.R. § 17.2.

/s/

Steven T. Kessel Administrative Law Judge