

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Defiance Road House, LLC,

Respondent.

Docket No. C-14-416
FDA Docket No. FDA-2013-H-1631

Decision No. CR3129

Date: February 25, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Defiance Road House, LLC, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

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 a minor and failed to verify that a cigarette purchaser was 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 \$500.

On January 8, 2014, 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 Defiance Roadhouse, an establishment that sells tobacco products and is located at 2999 Highway South, Defiance, Missouri 63341. Complaint ¶ 3.
- On January 24, 2013, during an inspection of Defiance Roadhouse, an FDA-commissioned inspector observed that “the establishment had a vending machine that provided a consumer direct access to cigarettes[,] . . . [and] [t]he vending machine was located in a customer-accessible portion of the establishment which is open to persons of all ages.” Complaint ¶ 10.
- On February 14, 2013, CTP issued a Warning Letter to Defiance Roadhouse explaining that the inspector’s January 24, 2013 observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(c). In addition to describing the violation, 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 violation. The letter also stated that it was Respondent’s responsibility to comply with the law. Complaint ¶ 10.
- On February 20, 2013, Tom Yeager, Respondent’s owner, responded by telephone to the Warning Letter on Respondent’s behalf. “Mr. Yeager stated he would remove the vending machine.” Complaint ¶ 11.

- On July 1, 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 cigarettes from a vending machine in Respondent's establishment . . . at approximately 12:43 PM[] 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 January 24, 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. Additionally, on July 1, 2013, a minor was able to enter Respondent's 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 \$500 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge