

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

FNG Enterprise
d/b/a Ten Mile House,

Respondent.

Docket No. C-13-834
FDA Docket No. FDA-2013-H-0644

Decision No. CR2878

Date: August 2, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, FNG Enterprise d/b/a Ten Mile House, that alleges facts and legal authority sufficient to justify imposing a \$250 civil money penalty. 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 assess a civil money penalty of \$250.

CTP began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that Respondent unlawfully used a vending machine to sell tobacco products and sold a tobacco product to a minor, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301-399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil monetary penalty of \$250 for these violations.

On June 6, 2013, CTP served the Complaint on Respondent by UPS, 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true[] and, if such facts establish liability under [the Act],” issue an initial decision by default and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Ten Mile House, an establishment that sells tobacco products and is located at 9420 Gravois Road, Saint Louis, Missouri 63123. Complaint ¶ 2.
- On May 17, 2012, an FDA-commissioned inspector observed two violations at Ten Mile House. First, in violation of 21 C.F.R. § 1140.14(a), “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes from a vending machine . . . at approximately 6:25 PM[.]” The inspector also noted a violation of 21 C.F.R. § 1140.14(c) because a minor had entered the establishment and purchased the tobacco product through a vending machine. Complaint ¶ 9.
- “[O]n July 19, 2012, CTP issued a Warning Letter to Ten Mile House.” The letter informed Respondent of the violations the FDA-commissioned inspector had observed on May 17, 2012, and explained that the FDA could initiate a civil money penalty or other regulatory action if Respondent failed to correct the violations. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Ten Mile House was responsible for complying with the law. Complaint ¶ 9.
- Respondent received the Warning Letter via UPS on July 20, 2012. The package was signed for by “Ginther.” CTP did not receive a response to the Warning Letter. Complaint ¶ 10.
- During a following two-part inspection conducted on December 3 and 14, 2012, FDA-commissioned inspectors documented another violation. The inspectors noted that Respondent maintained a vending machine and that “minors are

permitted in the establishment for meals,” in violation of 21 C.F.R. § 1140.14(c).
Complaint ¶ 1.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those regulations prohibit the sale of “cigarettes or smokeless tobacco to any person younger than 18 years of age[.]” 21 C.F.R. § 1140.14(a). Those regulations also require retailers to “sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine).” 21 C.F.R. § 1140.14(c). Vending machines are only 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, Respondent violated 21 C.F.R. § 1140.14(a) and (c). During two separate inspections, Respondent maintained a vending machine in a facility that allows minors to enter, in violation of 21 C.F.R. § 1140.14(c). Respondent also unlawfully used a vending machine to sell a package of cigarettes to a minor, in violation of 21 C.F.R. § 1140.14(a). Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed its third violation within a 24-month period, the maximum penalty for which is \$500. 21 C.F.R. § 17.2. CTP, however, has requested a civil money penalty in the amount of \$250, which is the maximum penalty for the second violation committed within a 12-month period. Therefore, I impose a civil money penalty in the amount of \$250.

/s/
Steven T. Kessel
Administrative Law Judge