

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Wolf's Tavern LLC
d/b/a Wolf's Tavern,

Respondent.

Docket No. C-13-876
FDA Docket No. FDA-2013-H-0697

Decision No. CR2877

Date: July 30, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Wolf's Tavern LLC d/b/a Wolf's Tavern, 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, on two separate occasions, Respondent unlawfully utilized a vending machine to sell tobacco products, 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 14, 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 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 Wolf’s Tavern, an establishment that sells tobacco products and is located at 400 South Johnson, New Athens, Illinois 62264. Complaint ¶ 2.
- On July 9, 2012, an FDA-commissioned inspector observed a violation at Wolf’s Tavern. “Specifically, during the July 9, 2012 inspection, an inspector observed a vending machine in the establishment.” In addition, “the bartender on duty told the inspector that minors are permitted to enter the establishment when accompanied by an adult.” Complaint ¶ 9.
- “[O]n October 18, 2012, CTP issued a Warning Letter to Wolf’s Tavern.” The letter informed Respondent of the violation the FDA-commissioned inspector had observed on July 9, 2012, and explained that FDA could initiate a civil money penalty or other regulatory action if Respondent failed to correct the violation. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Wolf’s Tavern was responsible for complying with the law. Complaint ¶ 9.
- Respondent’s owner responded to the Warning Letter on Respondent’s behalf by telephone on October 30, 2012. Respondent explained “he would restrict the establishment to customers 21 years and older, and that he would check identification of customers who appeared under 27 years of age at the point of entrance.” Complaint ¶ 10.
- CTP acknowledged Respondent’s communication in writing on December 20, 2012. CTP reminded Respondent of its responsibility to comply with the Act and regulations. Complaint ¶ 10.

- During another inspection on February 28, 2013, an FDA-commissioned inspector documented an additional violation. The inspector observed again that Respondent had “a vending machine in [Wolf’s Tavern] and . . . an employee on duty told the inspector that minors are permitted to enter the establishment when accompanied by an adult.” 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 provide that “a retailer may 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), unless the vending machines is “located in [a] facilit[y] 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(c) on two separate occasions. First, on July 9, 2012, Respondent had a vending machine in its establishment where minors were permitted to enter. Then, on February 28, 2013, Respondent again had a vending machine in the establishment. Therefore, Respondent’s actions on two separation occasions at the same retail outlet 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 second violation, after receiving a Warning Letter after the first violation, within a 12-month period, the maximum penalty for which is \$250. 21 C.F.R. § 17.2. And, CTP has requested a penalty in that amount. Therefore, I impose a civil money penalty in the amount of \$250.

/s/
Steven T. Kessel
Administrative Law Judge