

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Downtown Saloon, Inc. / Scott A. Warner
d/b/a Downtown Saloon,

Respondent.

Docket No. C-15-72
FDA Docket No. FDA-2014-H-1564

Decision No: CR3490

Date: December 1, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Downtown Saloon, Inc. / Scott A. Warner, d/b/a Downtown Saloon, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not 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 serving the 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 impermissibly sold cigarettes to a minor, failed to verify that a cigarette purchaser was 18 years of age or older, and utilized a vending machine to sell regulated tobacco products in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and

its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140 (2013). CTP seeks a civil money penalty of \$250.

On October 16, 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 proposed 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 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. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Downtown Saloon, an establishment that sells tobacco products and is located at 7 North King Street, Leesburg, Virginia 20176. Complaint ¶ 2.
- During an inspection of Respondent’s establishment on August 30, 2013, at approximately 11:22 AM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale . . . [.]” Finally, the inspector observed that the minor was able to purchase the Marlboro cigarettes from a vending machine. Complaint ¶ 9.
- On October 17, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from August 30, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a), (b)(1), and (c), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 9.
- Scott Warner, who identified himself as Respondent’s establishment’s owner, responded to the Warning Letter in an October 22, 2013 letter and January 6, 2014 telephone call. Mr. Warner “stated that on the date of the inspection, his ‘employee did not do his job properly,’ and noted that the employee had since

been terminated. He further stated that he would do his “best to ... comply with all laws, and regulations concerning tobacco products.” Mr. Warner also informed CTP that “he would either move the vending machine behind the bar or sell tobacco products from behind the bar without the vending machine.” Complaint ¶ 10.

- During a subsequent inspection of Respondent’s establishment on January 31, 2014, at an unspecified time, an FDA-commissioned inspector “observed a vending machine that is accessible to all customers in the facility, and the establishment’s owner told the inspector that minors are allowed to enter the facility before 9:00 PM” 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 distributed or offered for sale in any state 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). 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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Moreover, the regulations require retailers to sell cigarettes or smokeless tobacco exclusively in a direct, face-to-face exchange without the assistance of any mechanical device unless the facility ensures that no one younger than 18 years of age is present or permitted to enter at any time. 21 C.F.R. § 1140.14(c).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 30, 2013. That same date, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, on January 31, 2014, Respondent impermissibly maintained a vending machine in a facility that allows minors to enter, in violation of 21 C.F.R. § 1140.14(c). Respondent’s actions thus constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge