

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Jones 1902 Realty LLC,
d/b/a Jones Tavern

Respondent.

Docket No. C-15-9
FDA Docket No. FDA-2014-H-1499

Decision No. CR3470

Date: November 20, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Jones 1902 Realty LLC, d/b/a Jones Tavern that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,250. 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 \$2,250.

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 minors, failed to verify that cigarette purchasers were 18 years of age or older, utilized a vending machine to sell regulated tobacco products in a non-exempt facility, and offered tobacco products for sale using false or misleading advertising, 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 \$2,250.

On October 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 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 Jones Tavern, an establishment that sells tobacco products and is located at 1902 Lafayette Street, Scranton, Pennsylvania 18504. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on September 29, 2013, at approximately 4:57 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s 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 a tobacco product from [a] vending machine.” Complaint ¶ 11.
- On November 14, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from September 29, 2013. The letter explained that the observation 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 was responsible for complying with the law. Complaint ¶ 11.
- Sandra Golay responded to the Warning Letter by a January 7, 2014, email and a January 15, 2014, telephone call. “Ms. Golay stated that the establishment’s corrective actions were to post signage on [the] entrance door prohibiting anyone

under the age of 18 from entering the establishment and to instruct all bartenders to check identification of anyone entering the establishment that looks under the age of 27 and attempts to purchase cigarettes.” Complaint ¶ 12.

- During a subsequent two-part inspection of Respondent’s establishment conducted on March 23, 2014, and May 12, 2014, FDA-commissioned inspectors documented four violations: (1) the sale of Newport Box 100s cigarettes to a minor on March 23, 2014 at 3:58 PM; (2) a violation 21 C.F.R. § 1140.14(b)(1), as a result of not verifying the minor’s identification before the March 23, 2014 sale; (3) a violation of 21 C.F.R. § 1140.14(c), at an unspecified date and time, when “a person younger than 18 years of age was able to enter the establishment and purchase a tobacco product from the vending machine;” and (4) at an unspecified date and time, “[t]he cigarettes [in the vending machine in Respondent’s establishment] stocked to correspond with the ‘Camel Lights Hard Pack’ and ‘Marlboro Lights Low in Tar and Nicotine’ buttons [were] not labeled as such,” and “the buttons [used] the terms ‘low tar’ and ‘light.’” 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). A tobacco product is also misbranded under section 903 of the Act if its labeling is false or misleading in any particular or if it is offered for sale and its advertising is false or misleading in any particular. 21 U.S.C. § 387c(a)(1) and (a)(7)(A). 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 in a facility that does not ensure that no person 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 September 29, 2013, and March 23, 2013. Those same dates, Respondent 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). On September 29, 2013, and again during a two-part inspection on March 23, 2014, and May 12, 2014, Respondent then impermissibly maintained a vending

machine in a facility that allows minors to enter, in violation of 21 C.F.R. § 1140.14(c). Finally, during a two-part inspection on March 23, 2014, and May 12, 2014, Respondent violated the prohibition against offering tobacco products for sale using false or misleading advertising, 21 U.S.C. § 387c, when it sold cigarette packages that did not correspond to their labels on the vending machine and contained the labels “low tar” and “light.”

CTP has requested a civil fine of \$2,250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil penalty of \$2,250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge