Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

James K. Lee d/b/a Westwood Billiards,

Respondent.

Docket No. C-14-1027 FDA Docket No. FDA-2014-H-0535

Decision No. CR3278

Date: June 27, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, James K. Lee d/b/a Westwood Billiards, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$5,000. 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 \$5,000.

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 and failed to verify that a cigarette purchaser was 18 years of age or older, 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 (2012). CTP seeks a civil money penalty of \$5,000.

On May 6, 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 Westwood Billiards, an establishment that sells tobacco products and is located at 2207 South Westwood Boulevard, Poplar Bluff, Missouri 63901. Complaint ¶ 3.
- During an inspection of Respondent's establishment on December 23, 2013, at approximately 1:14 PM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]" The inspectors also documented that "the minor's identification was not verified before the sale" Complaint ¶ 10.

In a decision dated February 27, 2013, which became final on March 29, 2013, an Administrative Law Judge found:

- On February 8, 2012, Respondent used a vending machine in his establishment in violation of 21 C.F.R. § 1140.14(c).
- CTP informed Respondent of the alleged February 8, 2012 violation by Warning Letter dated March 29, 2012.
- On July 14, 2012, Respondent sold a package of Marlboro 100's cigarettes to a person younger than 18 years of age in violation of 21 C.F.R.

§ 1140.14(a). Respondent also failed to verify, by means of photo identification containing the bearer's date of birth, that the purchaser was 18 years of age or older in violation of 21 C.F.R. § 1140.14(b)(1).

James K. Lee d/b/a Westwood Billiards, DAB CR2711, at 2-4 (2013).

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 issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 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). Finally, the regulations require retailers to sell cigarettes and smokeless tobacco exclusively through a face-to-face exchange and without the assistance of a vending machine, 21 C.F.R. § 1140.14(c), except where the vending machine is located in a facility in which minors are prohibited from being present at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

An Administrative Law Judge previously found that Respondent committed three violations of regulations contained in 21 C.F.R. pt. 1140. *Lee*, DAB CR2711 at 3. Taking the above alleged facts as true, Respondent most recently violated the prohibition against selling cigarettes to any person younger than 18 years of age on December 23, 2013. 21 C.F.R. § 1140.14(a). On the 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). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$5,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed.

/s/

Steven T. Kessel Administrative Law Judge