

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Subgenius Entertainment LLC
d/b/a Goat Head Saloon,

Respondent.

Docket No. C-13-745
FDA Docket No. FDA-2013-H-0532

Decision No. CR2860

Date: July 18, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Subgenius Entertainment LLC d/b/a Goat Head Saloon, that alleges facts and legal authority sufficient to justify imposing a \$500 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 \$500.

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 sold individual cigarettes, sold a tobacco product to a minor, and failed to verify that the purchaser of the tobacco product was of sufficient age, 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 \$500 for these violations.

On May 31, 2013, CTP served the Complaint on Respondent by United States Postal Service Certified Mail, 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 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 a default judgment 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 Goat Head Saloon, an establishment that sells tobacco products and is located at 1423 South Country Club Drive, Suite 12, Mesa, Arizona 85210. Complaint ¶ 3.
- On May 10, 2012, an FDA-commissioned inspector observed that Respondent sold individual cigarettes. Complaint ¶ 10.
- “[O]n August 23, 2012, CTP issued a Warning Letter to Goat Head Saloon.” The letter informed Respondent of the violation the FDA-commissioned inspector had observed on May 10, 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 Goat Head Saloon was responsible for complying with the law. Complaint ¶ 10.
- Respondent received the Warning Letter on August 27, 2012. United Parcel Service delivered the letter to “MARKEE.” CTP received no response. Complaint ¶ 11.
- During a following inspection, FDA-commissioned inspectors documented two additional violations. “Specifically, a person younger than 18 years of

age was able to purchase a package of Marlboro cigarettes on December 14, 2012, at approximately 12:56 PM[.]” And, “the minor’s identification was not verified before the [December 14, 2012,] sale. . . .” 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 retailers from opening a cigarette or smokeless tobacco package “to sell or distribute individual cigarettes” 21 C.F.R. § 1140.14(d). They also prohibit the sale of “cigarettes or smokeless tobacco to any person younger than 18 years of age[.]” 21 C.F.R. § 1140.14(a). Finally, those regulations require a retailer to “verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]” 21 C.F.R. § 1140.14(b)(1).

Here, Respondent violated 21 C.F.R. § 1140.14(a), (b)(1), and (d). First, on May 10, 2012, Respondent unlawfully sold individual cigarettes in violation of 21 C.F.R. § 1140.14(d). Then, on December 14, 2012, Respondent unlawfully sold a tobacco product to a minor without verifying that the purchaser was not younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a) and (b)(1). Therefore, Respondent’s actions and omission 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 third violation within a 24-month period, the maximum penalty for which is \$500. 21 C.F.R. § 17.2. And, CTP has requested a civil money penalty in that amount. Therefore, I impose a civil money penalty in the amount of \$500.

/s/
Steven T. Kessel
Administrative Law Judge