

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Randall Garner,  
d/b/a Bacca Cigar Co.,

Respondent.

Docket No. C-15-180  
FDA Docket No. FDA-2014-H-1695

Decision No. CR3531

Date: December 23, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Randall Garner d/b/a Bacca Cigar Co., alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$2,000. 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 order that Respondent pay a civil money penalty in the amount of \$2,000.

CTP began this case by serving a 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's staff unlawfully sold tobacco products to a minor, failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, and utilized a self-service

display of tobacco products in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$2,000.

On October 29, 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 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. 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Bacca Cigar Co., an establishment that sells tobacco products and is located at 1707 West Kirby Avenue, Champaign, Illinois 61821. Complaint ¶ 3.
- During an inspection of Respondent's establishment on November 13, 2013, at an undisclosed time, an FDA-commissioned inspector observed Respondent "using a self-service display [of cigarette tobacco] in a non-exempt facility . . . ." The inspector also observed that minors were allowed to enter Respondent's establishment "when accompanied by a parent." Complaint ¶ 10.
- In a Warning Letter dated January 16, 2014, CTP informed Respondent of the inspector's November 13, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.16(c). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action. Complaint ¶ 10.
- In response to the Warning Letter, on March 18, 2014, Randall Garner, Respondent's owner, called CTP and sent an e-mail. "Mr. Garner stated that he changed the store policy and will no longer allow anyone under . . . 18 in [his] store." Complaint ¶ 11.

- During a subsequent inspection of Respondent's establishment conducted on April 25, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Bugler Turkish & Blended cigarette tobacco . . . at approximately 3:54 PM." The inspectors also documented that Respondent's staff "failed to verify [the minor's] . . . identification" before the sale on April 25, 2014, and utilized a "self-service display [of cigarette tobacco] on April 25, 2014 . . ." in a non-exempt facility.

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 sold or distributed 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 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 the verification, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Pursuant to 21 C.F.R. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer.

Taking the above alleged facts as true, Respondent utilized a self-service display in violation of 21 C.F.R. § 1140.16(c), on November 13, 2013 and April 25, 2014. Additionally, on April 25, 2014, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a). On that same date, Respondent violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchaser is 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 \$2,000 which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge