

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Big Charlies Truck Plaza, Inc.,

Respondent.

Docket No. C-14-1850
FDA Docket No. FDA-2014-H-1335

Decision No. CR3453

Date: November 12, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Big Charlies Truck Plaza, Inc., alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500. 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 \$500.

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 minors, and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, 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 \$500.

On September 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 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 Big Charlies Truck Plaza, Inc., an establishment that sells tobacco products and is located at 5792 Northampton Boulevard, Virginia Beach, Virginia 23455. Complaint ¶ 3.
- During an inspection of Respondent's establishment on September 26, 2013, at approximately 6:00 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes" Complaint ¶ 10.
- In a Warning Letter dated December 5, 2013, CTP informed Respondent of the inspector's September 26, 2013 observation, and that such an action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action. Complaint ¶ 10.
- CTP received a letter from Maggie Tucker, Respondent's general manager, dated December 16, 2013, responding to the Warning Letter on Respondent's behalf. "Ms. Tucker stated that Respondent took disciplinary action against the employee who was on duty when the minor purchased the tobacco product." Ms. Tucker went on to state that "Respondent met with all employees to discuss the establishment's 'absolute requirement to ask for ID'" Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on March 11, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport Box

cigarettes . . . at approximately 8:05 PM.” The inspectors also documented that “the minor’s identification was not verified before the sale” 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 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).

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 26, 2013 and March 11, 2014. Additionally, on March 11, 2014, Respondent violated the requirement that retailers verify, 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). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$500, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge