Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Corbet Turner and Samuel Turner
d/b/a Beer and Bottle Shoppe,

Respondent.

Docket No. C-13-989
FDA Docket No. FDA-2013-H-0829

Decision No. CR2933

Date: October 1, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Corbet Turner and Samuel Turner d/b/a Beer and Bottle Shoppe, alleging facts and legal authority sufficient to justify the imposition of 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 impermissibly used self-service displays in a non-exempt facility and that Respondent's staff unlawfully sold a regulated tobacco product to a minor, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of $500.

On August 16, 2013, 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 the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here. I conclude that it is based on the allegations of the Complaint and Respondent's failure to answer them.

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 Beer and Bottle Shoppe, an establishment that sells tobacco products and is located at 1889 South Business Highway 65, Hollister, Missouri 65672. Complaint ¶ 3.

- On June 8, 2012, an FDA-commissioned inspector observed a violation of the regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Respondent "violated 21 C.F.R. § 1140.16(c) by having 'self-service displays . . . that provide a consumer direct access to cigarettes and smokeless tobacco'" while "fail[ing] to ensure that minors are neither present nor permitted to enter at any time as the establishment is open to the general public during business hours." Complaint ¶ 10.

- On September 13, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from June 8, 2012. In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.

- On September 20, 2012, Karen Turner, manager of Beer and Bottle Shoppe, responded by telephone to the Warning Letter on behalf of Respondent. "Ms. Turner stated that the tobacco products were moved and . . . no longer self-service." Complaint ¶ 11.

- On January 11, 2013, and January 16, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 during another inspection of Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) on January 11, 2013, at approximately 5:42 PM CT, when "a person younger than 18 years of age was able to purchase a package of Skoal Long Cut Wintergreen smokeless tobacco." Additionally, on those inspection dates, Respondent's establishment had "a self-service display that include[d] loose cigarette tobacco in a customer[-]accessible part of the establishment." On those dates, the establishment was "open to persons of all ages[;] [t]herefore , th[e] facility d[id] not qualify as one where minors are not present or permitted to enter at any time." 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). Under 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. Examples of methods of sale that are not permitted include vending machines and self-service displays. However, vending machines and self-service displays are permitted if located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.

Here, Respondent violated 21 C.F.R. § 1140.16(c) when its staff sold cigarettes and smokeless tobacco in a manner other than a direct, face-to-face exchange with its customer on multiple occasions: June 8, 2012, January 11, 2013, and January 16, 2013. On those dates, Respondent's establishment was not exempt from the requirement that tobacco products be sold only via a direct, face-to-face exchange because the establishment was open to the general public. Additionally, on January 11, 2013, Respondent violated 21 C.F.R. § 1140.14(a) when its staff sold

smokeless tobacco to a minor. Respondent's actions on multiple occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of $500 is permissible under 21 C.F.R. § 17.2.

/s/

Steven T. Kessel
Administrative Law Judge