

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Homeport Trading, Inc.
d/b/a Cigar Q,

Respondent.

Docket No. C-13-1081
FDA Docket No. FDA-2013-H-0890

Decision No. CR2942

Date: October 4, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Homeport Trading, Inc. d/b/a Cigar Q, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$250.

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 on multiple occasions, 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 \$250.

On August 20, 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 Cigar Q, an establishment that sells tobacco products and is located at 19018 Lenton Place Southeast, Monroe, Washington 98272. Complaint ¶ 2.
- On July 19, 2012, during an inspection of Respondent's establishment, an FDA-commissioned inspector observed that the establishment contained "multiple customer[-]accessible shelves containing cigarette tobacco and smokeless tobacco[;] . . . a customer[-]accessible beverage cooler containing Grizzly and Copenhagen smokeless tobacco[;] . . . and Davidoff cigarettes in a customer[-]accessible display on the sales counter." In addition, "[d]uring the inspection, the clerk on duty told the inspector that minors are allowed to enter at any time." Complaint ¶ 9.
- On October 25, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from July 19, 2012. The letter explained that the inspector's observations constituted a violation of 21 C.F.R. § 1140.16(c) and advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violation. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 9.
- On January 7, 2013, Jong Ohm responded by e-mail to the Warning Letter on behalf of Respondent. "Mr. Ohm stated that the establishment does not

allow minors in at any time[,] and that the establishment moved the Davidoff cigarettes from the sales counter and relocated its beverage cooler with its smokeless tobacco behind the sales counter.” Complaint ¶ 10.

- On January 22, 2013, and February 12, 2013, FDA-commissioned inspectors conducted a two-part inspection of Respondent’s establishment. On those dates, the inspectors documented that “[t]he establishment ha[d] . . . multiple brands of smokeless tobacco and cigarette tobacco on a customer[-]accessible display in the middle of the establishment.” The inspectors also documented that “a person younger than 18 years of age was able to enter the establishment.” 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. The regulations prohibit the use of a self-service display as a method of sale for cigarettes and smokeless tobacco. 21 C.F.R. § 1140.16(c)(1). However, 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).

Here, Respondent violated 21 C.F.R. § 1140.16(c) when its staff offered cigarettes and smokeless tobacco for sale in a manner other than a direct, face-to-face exchange with its customers on July 19, 2012, January 22, 2013, and February 12, 2013. On those dates, Respondent impermissibly utilized self-service displays for regulated tobacco products because Respondent’s facility is not one where minors are prohibited from entering. 21 C.F.R. § 1140.16(c)(2)(ii). 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 \$250 is permissible under 21 C.F.R. § 17.2 and order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge