

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Jamuna Trade, Inc.
d/b/a Moe's Corner,

Respondent.

Docket No. C-14-1239
FDA Docket No. FDA-2014-H-0733

Decision No. CR3317

Date: August 4, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Jamuna Trade, Inc. d/b/a Moe's Corner, 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 impermissibly utilized a self-service display of smokeless tobacco in its establishment and that Respondent's staff unlawfully sold tobacco products to minors, 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 June 4, 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, 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 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 Moe's Corner, an establishment that sells tobacco products and is located at 851 North Wood River Avenue, Wood River, Illinois 62095. Complaint ¶ 3.
- During an inspection of the establishment conducted on January 31, 2012, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 4:53 PM CST." Complaint ¶ 12.
- On February 23, 2012, CTP issued a Warning Letter to Moe's Corner explaining that the inspector's January 31, 2012 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a). In addition to describing the violation, the letter 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 ¶ 12.
- The FDA did not receive a response to the Warning Letter, but delivery records show that an individual named "Butler" received it on February 24, 2012. Complaint ¶ 13.
- During another inspection of the establishment conducted on January 31, 2013, an FDA-commissioned inspector observed that Respondent had a self-service display containing "customer-accessible smokeless tobacco for sale on the customer side of the checkout counter." The inspector also noted that Respondent's

“establishment was open to the general public during business hours.” Complaint ¶ 10.

- On April 18, 2013, CTP issued a second Warning Letter to Moe’s Corner explaining that the inspector’s January 31, 2013 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c). In addition to describing the violation, the letter 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 ¶ 10.
- The FDA did not receive a response to the second Warning Letter, but delivery records show that an individual named “Butlex” received it on April 19, 2013. Complaint ¶ 11.
- On September 19, 2013, during a subsequent inspection of Respondent’s establishment, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase Skoal Berry Tobacco Blend Long Cut smokeless tobacco from a self-service display in Respondent’s establishment . . . at approximately 4:45 PM[.]” 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 Secretary issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). 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. Under 21 C.F.R.

§ 1140.16(c), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. A self-service display is a method of sale expressly prohibited by the regulations unless the self-service display is located in a facility in which 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 sold cigarettes to a minor on January 31, 2012, and smokeless tobacco to a minor on September 19, 2013. In addition, Respondent utilized a self-service display of smokeless tobacco in its business establishment on January 31, 2013, and September 19, 2013. On those dates, Respondent’s establishment was not exempt from the requirement that retailers sell smokeless tobacco only in direct, face-to-face exchanges between the retailer and the consumer because Respondent permitted minors to enter its establishment during business hours. Therefore, Respondent’s actions on multiple

occasions at the same retail outlet constitute violations of law that warrant a civil money penalty. Accordingly, I find that a civil money penalty of \$2,000 is permissible under 21 C.F.R. § 17.2.

 /s/
Steven T. Kessel
Administrative Law Judge