

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Gadd's Super Market, Inc.
d/b/a Gadd's IGA Foodliner,

Respondent.

Docket No. C-14-1190
FDA Docket No. FDA-2014-H-0696

Decision No. CR3303

Date: July 21, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Gadd's Super Market, Inc. d/b/a Gadd's IGA Foodliner, alleging facts and legal authority sufficient to justify imposing 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 utilized a self-service display of smokeless tobacco, 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 \$250.

On June 3, 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 Gadd's IGA Foodliner, an establishment that sells tobacco products and is located at RR 2 Box 8A, Alderson, West Virginia 24910. Complaint ¶ 2.
- During an inspection of the establishment conducted on April 25, 2013, an FDA-commissioned inspector observed that "the establishment, which was open to the public during business hours, had a customer-accessible shelving unit containing smokeless tobacco on the sales floor." Complaint ¶ 9.
- On May 16, 2013, CTP issued a Warning Letter to Gadd's IGA Foodliner explaining that the inspector's April 25, 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 ¶ 9.
- The FDA did not receive a response to the Warning Letter, but delivery records show that an individual named "Shafer" received it on May 17, 2013. Complaint ¶ 10.
- On October 29, 2013, and October 31, 2013, during a subsequent two-part inspection of Respondent's establishment, FDA-commissioned inspectors

documented that “the establishment, which [was] open to the general public during business hours, ha[d] a customer-accessible shelving unit containing smokeless tobacco on the sales floor.” 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. § 1140.16(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 utilized a self-service display of smokeless tobacco in its business establishment on April 25, 2013, October 29, 2013, and October 31, 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 \$250 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge