

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Martha Garmany  
d/b/a Discount Tobacco Outlet,

Respondent.

Docket No. C-13-341  
FDA Docket No. FDA-2013-H-0107

Decision No. CR2808

Date: May 30, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Martha Garmany d/b/a Discount Tobacco Outlet, that alleges 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 assess a civil money penalty of \$250.

CTP began this case by serving the 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 used a self-service display in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301-399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil monetary penalty of \$250 for this violation.

On April 16, 2013, CTP served the Complaint on Respondent by United States Postal Service Certified Mail, pursuant to 21 C.F.R. §§ 17.5 and 17.7.<sup>1</sup> 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 issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act],” issue a default judgment and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Discount Tobacco Outlet, an establishment that sells tobacco products and is located at 969 US Highway 431, Suite B, Boaz, Alabama 35957. Complaint ¶ 2.
- On January 30, 2012, an FDA-commissioned inspector observed that Respondent failed to sell cigarettes or smokeless tobacco in a face-to-face exchange only, as required under 21 C.F.R. § 1140.16(c), because Discount Tobacco Outlet is not an establishment that ensures that minors are neither present nor permitted to enter at any time. Complaint ¶ 9.
- “[O]n March 8, 2012, CTP issued a Warning Letter to Discount Tobacco Outlet.” Complaint ¶ 9. The letter noted the violation the FDA-commissioned inspector had observed on January 30, 2012, and explained that if Respondent failed to correct the violation, Respondent could face a civil money penalty or other regulatory action. Complaint ¶ 9. Moreover, CTP explained that the warning letter was not intended to provide an exhaustive list of violations and that Discount Tobacco Outlet was responsible for complying with the law. Complaint ¶ 9.

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<sup>1</sup> CTP served Respondent at a Post Office Box address. Mail from the Civil Remedies Division, Departmental Appeals Board addressed to Respondent’s establishment was returned as “undeliverable as addressed, unable to forward.”

- Respondent received the warning letter on March 9, 2012, via UPS, and “Starder” signed for the delivery. Complaint ¶ 10. CTP, however, did not receive a response. Complaint ¶ 10.
- During a subsequent two-part inspection on June 15 and June 25, 2012, FDA-commissioned inspectors documented another violation of 21 C.F.R. § 1140.16(c), “for using a self-service display” in a facility where “minors are permitted to enter . . . when accompanied by an adult.” Complaint ¶ 1.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those regulations require a retailer to “sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer.” 21 C.F.R. § 1140.16(c)(1). Those regulations also prohibit a retailer from selling cigarettes and smokeless tobacco through “impersonal” modes of sale, such as self-service displays and vending machines. 21 C.F.R. § 1140.16(c)(1). The limitations of 21 C.F.R. § 1140.16(c)(1) do not apply if “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) twice by selling tobacco products through a self-service display in a facility where minors may enter. The first violation occurred on January 30, 2012. The second violation occurred during the two-part inspection performed on June 15, 2012, and June 25, 2012. Therefore, Respondent’s actions constitute violations of the Act for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed a subsequent violation after having received a warning letter for its first violation, within a 12-month period. The maximum penalty for a second violation is \$250. 21 C.F.R. § 17.2. CTP has requested a civil money penalty in that amount. Therefore, I impose a civil money penalty in the amount of \$250.

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/s/  
Steven T. Kessel  
Administrative Law Judge