

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

North End Boat Club,

Respondent.

Docket No. C-13-456  
FDA Docket No. FDA-2013-H-0214

Decision No. CR2751

Date: April 9, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, North End Boat Club, 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 used a vending machine for tobacco products in a non-exempt facility and failed to ensure specific tobacco-related items complied with applicable federal requirements, 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 February 26, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), 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 ordering Respondent to pay the full amount of the proposed penalty. Respondent did not file an answer within the time provided by regulation.

I am required to issue a default judgment 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, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically:

- Respondent owns North End Boat Club, a business that sells tobacco products and is located at 282 Merrimac Street, Newburyport, Massachusetts 01950.
- On December 2, 2011, an FDA-commissioned inspector observed violations while inspecting Respondent's establishment. These violations included the following: Respondent sold cigarettes or smokeless tobacco in a manner other than a direct, face-to-face exchange with its customer in a facility that does not ensure that no person younger than 18 years of age is present, or permitted to enter, at any time, in violation of 21 C.F.R. §§ 1140.14(c) and 1140.16(c); and Respondent failed to remove or bring into compliance all violative items that did not meet federal requirements in violation of 21 C.F.R. § 1140.14(e).
- On January 19, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from December 2, 2011, and advising Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.

- The FDA did not receive a response to the Warning Letter, but the delivery records show that “Hawkes” received the Warning Letter on January 20, 2012.
- On July 20, 2012, FDA commissioned inspectors documented an additional violation during a subsequent inspection of the establishment. Specifically, the establishment contained a vending machine for tobacco products and the bartender on duty at the time of the inspection admitted that the establishment permitted minors to enter when accompanied by an adult.

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. §§ 1140.14(c) and 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 unless the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. Under 21 C.F.R. § 1140.14(e), retailers must ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer’s establishment and that do not comply with the requirements of 21 C.F.R. Part 1140, are removed or brought into compliance with these requirements.

Here, Respondent sold cigarettes or smokeless tobacco at the establishment in a manner other than a direct, face-to-face exchange on December 2, 2011. On that date, Respondent’s establishment was not exempt from the requirement that tobacco products be sold only via a direct, face-to-face exchange because minors were permitted to enter the establishment if accompanied by an adult. Also on December 2, 2011, Respondent had items in the establishment that did not comply with applicable federal regulations, and these items were neither removed nor brought into compliance with the requirements. On July 20, 2012, Respondent had a vending machine for tobacco products at the establishment but continued to allow minors to enter the establishment if accompanied by an adult. These actions and omissions by Respondent constitute violations of law for which a civil money penalty is merited. Therefore, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2 and enter a default judgment against Respondent with an order that Respondent pay a civil money penalty in that amount.

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/s/  
Steven T. Kessel  
Administrative Law Judge