

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

On The Way Mini Mart, Inc.,

Respondent.

Docket No. C-14-217  
FDA Docket No. FDA-2013-H-1405

Decision No. CR3073

Date: January 9, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against On The Way Mini Mart, Inc. (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 \$500.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent utilized a self-service display of regulated tobacco products in a non-exempt facility, sold a regulated tobacco product to a minor, and failed to verify that a purchaser of a tobacco product was of sufficient age, 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.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on November 27, 2013, via United Parcel Service. The Complaint and accompanying cover letter stated that within 30 days, Respondent must take one of the following three actions: pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP further explained that if Respondent did not comply with one of the actions within 30 days, an Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has neither filed an Answer within the time provided by regulation, nor 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 an initial decision and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns On The Way Mini Mart, an establishment that sells tobacco products and is located at 9356 West State Road 44, Manilla, Indiana 46150. Complaint ¶ 3.
- On September 5, 2012, an FDA-commissioned inspector observed Respondent “using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c).” Specifically, the facility, “which was opened to the general public, had customer-accessible shelves containing cigarette tobacco and smokeless tobacco on the sales floor.” Complaint ¶ 10.
- On December 6, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from September 5, 2012. The letter explained that the observation constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter also stated that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- On December 19, 2012, an unidentified person responded in writing to the Warning Letter on Respondent’s behalf. “The response stated that a lock was placed on the case that contained the tobacco products, and that a

notice was [also] placed on the case indicating that it was ‘not a self-service display.’” Complaint ¶ 11.

- During a subsequent inspection conducted on June 6, 2013, and June 11, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. Specifically, “a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco on June 6, 2013, at approximately 10:00 AM[.]” The inspectors also documented that “the minor’s identification was not verified before the sale . . . on June 6, 2013 . . . .” Complaint ¶ 1.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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). *See* 21 U.S.C. § 387(a)(7)(B); 21 C.F.R.

§ 1140.1(b). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). Retailers are required to verify, by means of photo identification containing the purchaser’s date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Pursuant to 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. Self-service displays are a method of sale that is not permitted under the regulations, 21 C.F.R.

§ 1140.16(c)(1), except when 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).

In the present case, on September 5, 2012, Respondent utilized a self-service display in violation of 21 C.F.R. § 1140.16(c). On June 6, 2013, Respondent sold a regulated tobacco product to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a), and failed to verify by means of photographic identification that the purchaser of the tobacco product was of sufficient age, in violation of 21 C.F.R. § 1140.14(b)(1). Respondent’s actions and omissions at the same retail outlet constitute violations of law that warrant a civil money penalty.

