

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Walleye Mart, Inc.  
d/b/a Potholes General Store,

Respondent.

Docket No. C-13-970  
FDA Docket No. FDA-2013-H-0806

Decision No. CR2899

Date: August 23, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Walleye Mart, Inc. d/b/a Potholes General Store (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 began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that Respondent unlawfully sold a tobacco product to a minor on two separate occasions 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. CTP seeks a civil money penalty of \$500 for these violations.

On July 10, 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 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 stated that if Respondent does not comply with one of the actions within 30 days, an Administrative Law Judge (ALJ) may 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 Potholes General Store, an establishment that sells tobacco products and is located at 6897 Highway 262 Southeast, Othello, Washington 99344. Complaint ¶ 3.
- On July 19, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § Part 1140 at Potholes General Store. The inspector observed that “a person younger than 18 years of age was able to purchase a package of Camel Filters cigarettes . . . at approximately 10:27 AM PT.” Complaint ¶ 10.
- “[O]n October 4, 2012, CTP issued a Warning Letter to Potholes General Store.” The letter informed Respondent of the violations the FDA-commissioned inspector observed on July 19, 2012, and explained that Respondent’s failure to correct the violations “may result in a civil money penalty . . . or other regulatory action by the FDA.” Moreover, CTP further explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Respondent was responsible for complying with the law. Complaint ¶ 10.
- The “FDA did not receive a response to the Warning Letter.” “UPS records show that the Warning Letter was received on October 5, 2012, by ‘Mckernan’.” Complaint ¶ 11.

- On December 20, 2012, FDA-commissioned inspectors documented two additional violations at Respondent's establishment. First, "a person younger than 18 years of age was able to purchase a package of Marlboro Smooth cigarettes . . . at approximately 1:40 PM PT." The inspector also documented that "the minor's identification was not verified before the sale . . . ." Complaint ¶ 1.
- On December 26, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on December 20, 2012, and "that during the inspection a minor entered the establishment and purchased a regulated tobacco product." The notice also warned Respondent that other potential violations of the federal tobacco law may have been observed and if CTP determined that there were additional violations of federal law, the establishment may receive further notification from the FDA. Complaint ¶ 2.

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. § 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). The regulations also require retailers 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).

In the present case, Respondent violated 21 C.F.R. § 1140.14(a) on two separate occasions and violated 21 C.F.R. § 1140.14(b)(1) once. First, on July 19, 2012, Respondent unlawfully sold a regulated tobacco product to a minor. Subsequently, on December 20, 2012, Respondent again sold a regulated tobacco product to a minor and failed to verify, by means of photo identification, that the purchaser was 18 years of age or older. Therefore, Respondent's actions on two separate occasions constitute violations of law for which a civil money penalty is warranted.

The regulations require me to impose a civil money penalty that is either the maximum amount provided for by law, or the amount sought in the Complaint, whichever amount is smaller. 21 C.F.R. § 17.11(a)(1); 21 C.F.R. § 17.11(a)(2). Respondent received a Warning Letter after the first violation and subsequently committed an additional violation within a 24-month period. The regulations provide that the maximum penalty for this action is \$500. 21 C.F.R. § 17.2. In its

