

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Malwa Petro Inc.
d/b/a Quick-E-Fill Store/Phillips 66,

Respondent.

Docket No. C-13-1113
FDA Docket No. FDA-2013-H-0922

Decision No. CR2957

Date: October 22, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Malwa Petro Inc. d/b/a Quick-E-Fill (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$250 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 \$250.

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 on two separate occasions, Respondent unlawfully sold a 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. CTP seeks a civil money penalty of \$250 for these violations.

On August 21, 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 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 Quick-E-Fill Store/Phillips 66, an establishment that sells tobacco products and is located at 1215 South Randolph Street, Garrett, Indiana 46738. Complaint ¶ 3.
- On August 18, 2012, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Quick-E-Fill Store/Phillips 66. Specifically, the inspector observed that “a person younger than 18 years of age was able to purchase a package of Longhorn Long Cut Wintergreen smokeless tobacco . . . at approximately 8:10 PM.” Complaint ¶ 10.
- “[O]n November 1, 2012, CTP issued a Warning Letter to Quick-E-Fill Store/Phillips 66.” The letter informed Respondent of the violations the FDA-commissioned inspector observed at the establishment on August 18, 2012, and warned Respondent that failure to correct the violation “may result in a civil money penalty action, or other regulatory action by [the] FDA.” 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. The CTP did not receive a response to the warning letter. “UPS records show the Warning Letter was received on November 2, 2012, by ‘Graft.’” Complaint ¶¶ 10, 11.

- On February 13, 2013, FDA-commissioned inspectors documented an additional violation of 21 C.F.R. Part 1140 at Respondent's retail outlet. The inspectors documented a violation of 21 C.F.R. § 1140.14(a) when "a person younger than 18 years of age was able to purchase a package of Grizzly Premium Wintergreen Long Cut smokeless tobacco . . . at approximately 4:51 PM ET." Complaint ¶ 1.
- On February 19, 2013, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on February 13, 2013, and "that during the inspection a minor was able to enter the establishment and purchase 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.

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). 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 committed three violations of 21 C.F.R. Part 1140 within a 12-month period. First, on August 18, 2012, Respondent unlawfully 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. 21 C.F.R. § 1140.14(a)-(b)(1). During a subsequent inspection, on February 13, 2013, an FDA-inspector documented that Respondent unlawfully sold a regulated tobacco product to a minor. 21 C.F.R. § 1140.14(a). Respondent's actions and omissions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

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)-(2). The maximum penalty for these actions is \$500. *See* 21 C.F.R. § 17.2. In its Complaint, however, CTP

seeks a civil money penalty in the amount of \$250. Accordingly, I find that a civil money penalty in the amount of \$250 is permissible and order it imposed.

/s/

Steven T. Kessel
Administrative Law Judge