Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Plymouth Gas and Grocery Inc. d/b/a Plymouth Red D Mart,

Respondent.

Docket No. C-13-734 FDA Docket No. FDA-2013-H-0530

Decision No. CR2840

Date: June 24, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Plymouth Gas and Grocery Inc. d/b/a Plymouth Red D Mart, that 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, on two separate occasions, Respondent unlawfully sold a tobacco product to a minor and failed to verify that the purchaser of the 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 monetary penalty of \$500 for these violations.

On May 9, 2013, CTP served the Complaint on Respondent by United Parcel Service, 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, an 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 Plymouth Red D Mart, an establishment that sells tobacco products and also operates as a Marathon Gas Station. The establishment is located at 422 North Michigan Street, Plymouth, Indiana 46563. Complaint ¶ 3.
- On June 13, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) for "[s]elling tobacco products to a minor" and a violation of 21 C.F.R. § 1140.14(b)(1) for "[f]ailing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth[.]" Complaint ¶ 10.
- "[O]n August 16, 2012, CTP issued a Warning Letter to Plymouth Red D Mart/Marathon." The letter informed Respondent of the violations the FDA-commissioned inspector had observed on June 13, 2012, and explained that Respondent could face a civil money penalty or other regulatory action if it failed to correct the violations. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Plymouth Red D Mart/Marathon was responsible for complying with the law. Complaint ¶ 10.
- The manager of Plymouth Red D Mart/Marathon responded to the Warning Letter on behalf of Respondent on August 18, 2012. She explained that she

had "spoke[n] to all employees regarding the violations" and that she had "installed a 'Check ID and Birthdate' reminder on the register that is prompted when a tobacco product is being purchased[.]" She also informed CTP that she "placed a note on the counter instructing tobacco purchasers to be ready to present identification." Complaint ¶ 11.

- On October 16, 2012, CTP acknowledged that it had received Respondent's response. CTP also reminded Respondent that it had a continuing duty to comply with the law. Complaint ¶ 11.
- During a following inspection, FDA-commissioned inspectors documented two additional violations. "Specifically, a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Wintergreen smokeless tobacco on December 9, 2012, at approximately 1:40 PM[.]" Also, "the minor's identification was not verified before the [December 9, 2012,] sale. . . ." Complaint ¶ 1.
- CTP informed Respondent on December 18, 2012, of the December 9, 2012, inspection and documented violations through a Notice of Compliance Check Inspection. The Notice warned "that other potential violations of federal tobacco law may have been observed," and, if violations had occurred, FDA could notify Respondent further. 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. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). Those 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). Those regulations also require a retailer to "verify by means of photographic identification containing the bearer's date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]" 21 C.F.R. § 1140.14(b)(1).

Here, Respondent violated both 21 C.F.R. § 1140.14(a) and (b)(1). First, on June 13, 2012, Respondent unlawfully sold a tobacco product to a minor and failed to verify that the purchaser was of sufficient age. Then, on December 9, 2012, Respondent again unlawfully sold a tobacco product to a minor without verifying the purchaser's age. Therefore, Respondent's actions and omissions on two separate occasions 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 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 fourth violation within a 24-month period, the maximum penalty for which is \$2000. 21 C.F.R. § 17.2. CTP, however, requested a civil money penalty in the amount of \$500. 21 C.F.R. § 17.2. Therefore, I impose a civil money penalty in the amount of \$500.

Steven T. Kessel Administrative Law Judge