

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Paul's Supermarket, Inc.

Respondent.

Docket No. C-13-1313
FDA Docket No. FDA-2013-H-1117

Decision No. CR3011

Date: November 26, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Paul's Supermarket, Inc., that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. Respondent did not 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 serving the 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 impermissibly and repeatedly sold cigarettes to minors, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$500.

On September 26, 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 proposed 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Paul’s Supermarket, an establishment that sells tobacco products and is located at 1002 South Aurora Street, Eldon, Missouri 65026. Complaint ¶ 3.
- On July 21, 2011, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) at Respondent’s establishment when “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . at approximately 12:01 PM CT.” Complaint ¶ 12.
- On October 27, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from July 21, 2011. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state 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 ¶ 12.
- Tom Burditt, Respondent’s Store Manager, replied to the Warning Letter by telephone on November 4, 2011. “Mr. Burditt stated that it is Respondent's policy to check the identification of any person under age 27 who is attempting to buy tobacco products[;] . . . Respondent would retrain all regular employees and . . . all seasonal employees would be required to receive retraining before being allowed to work[;] . . . [and] any employee

who is found to have sold to a minor will be subject to dismissal and . . . any employee who fails to card someone who appears to be under 27 will be subject to disciplinary action.” Complaint ¶ 13.

- On February 25, 2012, FDA-commissioned inspectors documented an additional violation of 21 C.F.R. Part 1140 at Respondent’s establishment. 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 L&M cigarettes . . . at approximately 8:24 AM CT.” Complaint ¶ 10.
- CTP filed a civil money penalty action against Respondent on June 20, 2012, CRD Docket Number C-12-853. The civil money penalty action concluded when the Administrative Law Judge closed the case after the Respondent paid CTP an agreed-upon penalty. Complaint ¶¶ 10, 11.
- On March 29, 2013, FDA-commissioned inspectors documented another violation of 21 C.F.R. § 1140.14(a) at Respondent’s establishment when “a person younger than 18 years of age was able to purchase a package of Pall Mall Red cigarettes . . . at approximately 2:19 PM CT.” Complaint ¶ 1.

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 distributed or offered for sale in any state 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). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

Taking the above alleged facts as true, Respondent had three violations of regulations contained in 21 C.F.R. Part 1140 within a twenty-one month period. Specifically, Respondent had a violation on July 21, 2011, a violation on February 25, 2012, and a violation on March 29, 2013. Respondent’s actions on each occasion violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

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)(1)-(2). The regulations currently allow a maximum penalty of \$500 for a third violation within a twenty-one month period, 21 C.F.R. § 17.2, and CTP has requested a fine in that amount. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge