Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Safeway Inc. d/b/a Safeway Fuel Station 2640,

Respondent.

Docket No. C-14-1108 FDA Docket No. FDA-2014-H-0618

Decision No. CR3286

Date: July 10, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Safeway Inc. d/b/a Safeway Fuel Station 2640 (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 initiated 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's staff impermissibly sold regulated tobacco products to minors and failed to verify that a cigarette purchaser was of sufficient age, 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.

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On May 21, 2014, 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 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 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. 21 C.F.R. § 17.11.

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 Safeway Fuel Station 2640, an establishment that sells tobacco products and is located at 13308 Meridian East, Puyallup, Washington 98373. Complaint ¶ 3.
- On September 27, 2012, CTP issued a Warning Letter to Respondent regarding alleged violations of 21 C.F.R. Part 1140 that occurred at Respondent's establishment on July 16, 2012. The letter stated that failure to correct the violations may result in a civil money penalty action, or other regulatory action by the FDA. August 12, 2013 Complaint ¶ 10.
- On August 16, 2013, CTP initiated a civil money penalty action dated August 12, 2013, against Respondent, CRD Docket Number C-13-1145, "for [multiple] violations of 21 C.F.R. Part 1140 within a twelve-month period." Those violations included a violation of 21 C.F.R. § 1140.14(a) and (b)(1) on July 16, 2012, and one violation of 21 C.F.R. § 1140.14(a) for selling tobacco products to a minor on January 17, 2013. Complaint ¶ 10; August 12, 2013 Complaint ¶ 1
- Rick Whidden settled the claims on Respondent's behalf when "[he] admitt[ed] that the violations described in the Complaint filed in FDA Docket Number FDA-2013-H-0940, CRD Docket Number C-13-1145 occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the

¹CTP initiated a previous action against Respondent by filing an Administrative Complaint for civil money penalties with CRD dated August 12, 2013 (August 12, 2013 Complaint). CTP attached the August 12, 2013 Complaint to the Complaint it filed when it initiated the present matter.

violations may be counted in determining the total number of violations for purposes of future enforcement actions." Complaint ¶ 11

During a subsequent inspection of Respondent's establishment FDAcommissioned inspectors documented that "a person younger than 18 years of age was able to purchase package of Marlboro cigarettes on November 14, 2013, at approximately 10:25 AM." 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). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent committed four violations of 21 C.F.R. Part 1140 within a twenty-four month period. Specifically, on July 16, 2012, January 17, 2013, and November 14, 2013, Respondent unlawfully sold a regulated tobacco product to a minor. 21 C.F.R. § 1140.14(a). Additionally, on July 16, 2012, Respondent failed to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions and omissions constitute violations of law that merit a civil money penalty. Accordingly, I find that a civil money penalty in the amount of \$500 is permissible and order it imposed. 21 C.F.R. § 17.2.

/s/ Steven T. Kessel Administrative Law Judge