

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1401)

Complainant

v.

Safeway Inc.
d/b/a Safeway Gas Station 1129,

Respondent.

Docket No. C-14-1911

Decision No. CR3473

Date: November 21, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Safeway Inc., d/b/a Safeway Gas Station 1129, at 10276 Southern Maryland Boulevard, Dunkirk, Maryland 20754, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Safeway impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Safeway had previously admitted to three violations of C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent Safeway.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 23, 2014, CTP served the complaint on Respondent Safeway by United Parcel Service. 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 in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent Safeway has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to Respondent Safeway on November 29, 2012, citing violations¹ of 21 C.F.R. pt. 1140 on November 5, 2012, at Respondent's business establishment, 10276 Southern Maryland Boulevard, Dunkirk, Maryland 20754;
- On January 6, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-393, FDA Docket Number FDA-2013-H-1602, against Respondent Safeway for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred on November 5, 2012, and July 25, 2013;
- The previous action concluded when William Harris, Respondent's authorized representative, settled the claims on Respondent's behalf. On February 7, 2014, Mr. Harris signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on March 12, 2014;
- At approximately 12:02 p.m. on March 14, 2014, at Respondent's business establishment, 10276 Southern Maryland Boulevard, Dunkirk, Maryland 20754, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspectors also documented that Respondent's staff failed to verify, by means of

¹ In the complaint, CTP describes the action or actions that took place at Respondent Safeway's business establishment on November 5, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint dated December 13, 2013, and attached to the present complaint, however, CTP described two discrete violations at Respondent Safeway's business establishment on November 5, 2012: a violation of 21 C.F.R. § 1140.14(a) and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on November 5, 2012, was a typographical error.

photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent Safeway's liability 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. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Further, under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

Under 21 C.F.R. § 17.2, a \$5,000 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,000 against Respondent Safeway Inc., d/b/a Safeway Gas Station 1129. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge