

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-0905)

Complainant

v.

Berhane Kebede d/b/a 7-Eleven 11647,

Respondent.

Docket No. C-14-1401

Decision No. CR3358

Date: September 5, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Berhane Kebede d/b/a 7-Eleven 11647, at 5415 Kenilworth Avenue, Riverdale, Maryland 20737, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that 7-Eleven 11647 unlawfully 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, 21 C.F.R. pt. 1140. CTP seeks to impose a \$250 civil money penalty against Respondent 7-Eleven 11647.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 8, 2014, CTP served the complaint on Respondent 7-Eleven 11647 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 7-Eleven 11647 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:

- At Respondent's business establishment, 5415 Kenilworth Avenue, Riverdale, Maryland 20737, on July 25, 2013, at approximately 12:41 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Newport Box cigarettes to a person younger than 18 years of age;
- In a warning letter issued on September 5, 2013, CTP informed Respondent of the inspector's observation from July 25, 2013, and that such an action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that if Respondent failed to correct its violation, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 5415 Kenilworth Avenue, Riverdale, Maryland 20737, on November 6, 2013, at approximately 11:37 AM, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent'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 or smokeless tobacco to any person younger than 18 years of age.

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

