

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2013-H-0809)

Complainant

v.

Kuma H. Mamie
d/b/a 7-Eleven #22921,

Respondent.

Docket No. C-13-973

Decision No. CR2932

Date: September 26, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Kuma H. Mamie d/b/a 7-Eleven #22921, at 8101 Fenton Street, Silver Spring, Maryland 20910, 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 #22921 impermissibly sold cigarettes to a minor on two separate occasions and failed to verify the purchaser's age by means of photo identification containing a date of birth, violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose a \$500 civil money penalty against Respondent 7-Eleven #22921.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 10, 2013, CTP served the complaint on Respondent 7-Eleven #22921 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 #22921 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, 8101 Fenton Street, Silver Spring, Maryland 20910, on August 2, 2012, an FDA-commissioned inspector observed a sale of cigarettes to a person younger than 18 years of age;
- At Respondent's business establishment, 8101 Fenton Street, Silver Spring, Maryland 20910, on August 2, 2012, an FDA-commissioned inspector observed that staff failed to verify, by means of photo identification containing the bearer's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age;
- In a warning letter dated October 11, 2012, CTP informed Respondent of the inspector's August 2, 2012 observations, and that such actions violate federal law, 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 2:07 p.m. ET on December 13, 2012, at Respondent's business establishment, 8101 Fenton Street, Silver Spring, Maryland 20910, an FDA commissioned inspector observed the sale of a package of Newport Box cigarettes to a person younger than 18 years of age; staff also failed to verify, by means of photo identification containing the bearer's date of birth, the purchaser's age.

These facts establish Respondent 7-Eleven #22921'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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 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. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of

