

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1789)

Complainant,

v.

Highland Lakes Gas LLC
d/b/a Delta,

Respondent.

Docket No. C-15-276

Decision No. CR3547

Date: January 2, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Highland Lakes Gas LLC d/b/a Delta, at 189 Breakneck Road, Highland Lakes, New Jersey 07422 and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Delta unlawfully sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that tobacco 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. CTP seeks to impose a \$500 civil money penalty against Respondent Delta.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 6, 2014, CTP served the complaint on Respondent Delta 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 Delta 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, 189 Breakneck Road, Highland Lakes, New Jersey 07422, on November 16, 2013, at approximately 4:13 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Copenhagen Long Cut Wintergreen smokeless tobacco to a person younger than 18 years of age. The inspector also observed that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older;
- In a warning letter issued on January 30, 2014, CTP informed Respondent of the inspector's observations from November 16, 2013, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that if Respondent failed to correct its violations, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 189 Breakneck Road, Highland Lakes, New Jersey 07422, on May 12, 2014, at approximately 6:32 PM, FDA-commissioned inspectors documented Respondent's staff selling a package of Kodak Premium Wintergreen smokeless tobacco to a person younger than 18 years of age. The inspectors also observed that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older;

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.

