

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2150)

Complainant,

v.

Arabo Enterprises, Inc.
d/b/a Graham's Party Shoppe,

Respondent.

Docket No. C-15-626

Decision No. CR3646

Date: February 11, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Arabo Enterprises, Inc. d/b/a Graham's Party Shoppe, at 15801 Plymouth Road, Detroit, Michigan 48227, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Graham's Party Shoppe impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140 (2013). CTP seeks to impose a \$250 civil money penalty against Graham's Party Shoppe.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 15, 2014, CTP served the complaint on Respondent Graham's Party Shoppe 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 Graham's Party Shoppe 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:

- On December 14, 2013, at 4:53 p.m., at Respondent's business establishment, 15801 Plymouth Road, Detroit, Michigan 48227, an FDA-commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older;
- In a warning letter dated March 6, 2014, CTP informed Respondent of the inspector's December 14, 2013 observations, and that such actions violate federal laws, 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1). The letter further warned that Respondent's failure to correct the violations could result in a civil money penalty or other regulatory action;
- At approximately 1:35 p.m. on June 14, 2014, at Respondent's business establishment, 15801 Plymouth Road, Detroit, Michigan 48227, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes.

These facts establish Respondent Graham's Party Shoppe'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). 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).

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

