

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-0285)

Complainant

v.

Gift Shop III, Inc. / Frank Younus
d/b/a Embassy Gift Shop,

Respondent.

Docket No. C-15-1099

Decision No. CR3754

Date: April 2, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Gift Shop III, Inc. / Frank Younus, d/b/a Embassy Gift Shop, at 110 West Washington Street, Indianapolis, Indiana 46204, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Embassy Gift Shop 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. CTP seeks to impose a \$500 civil money penalty against Respondent Embassy Gift Shop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on February 3, 2015, CTP served the complaint on Respondent Embassy Gift Shop 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 Embassy Gift Shop 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 approximately 2:40 PM on October 7, 2012, at Respondent's business establishment, 110 West Washington Street, Indianapolis, Indiana 46204 an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. The inspector also observed 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 November 29, 2012, CTP informed Respondent of the inspector's October 7, 2012 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (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 11:50 AM on August 17, 2014, at Respondent's business establishment, 110 West Washington Street, Indianapolis, Indiana 46204, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. 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.

These facts establish Respondent Embassy Gift Shop'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. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Gift Shop III, Inc. / Frank Younus, d/b/a Embassy Gift Shop. 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