

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2013-H-1671)

Complainant

v.

Greyhound Package Store, Inc.,

Respondent.

Docket No. C-14-453

Decision No. CR3148

Date: March 10, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Greyhound Package Store, Inc., at 676 Broadway, Raynham, Massachusetts 02767, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Greyhound Package Store impermissibly sold cigarettes to minors and failed to verify a 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 \$250 civil money penalty against Respondent Greyhound Package Store.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 15, 2014, CTP served the complaint on Respondent Greyhound Package Store 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 Greyhound Package Store 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 12:05 PM on May 4, 2013, at Respondent's business establishment, 676 Broadway, Raynham, Massachusetts 02767, an FDA-commissioned inspector observed Respondent's staff sell a package of Marlboro cigarettes to a person younger than 18 years of age. The inspector also observed that Respondent's staff failed to verify the purchaser's age by means of photo identification containing a date of birth;
- In a warning letter dated May 16, 2013, CTP informed Respondent of the inspector's May 4, 2013 observations, 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, a civil money penalty action or other regulatory action could occur;
- At approximately 2:42 PM on August 10, 2013, at Respondent's business establishment, 676 Broadway, Raynham, Massachusetts 02767, an FDA-commissioned inspector documented that Respondent's staff sold a package of Marlboro cigarettes to a person younger than 18 years of age.

These facts establish Respondent Greyhound Package Store'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 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 photo identification containing the bearer's date of birth, that no cigarette purchaser is younger than 18 years of age.

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

