

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-0660)

Complainant

v.

Guadalupana Grocery Deli LP
d/b/a Guadalupana Grocery and Deli,

Respondent.

Docket No. C-14-1159

Decision No. CR3304

Date: July 22, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Guadalupana Grocery Deli LP d/b/a Guadalupana Grocery and Deli, at 1205 River Avenue, Lakewood, New Jersey 08701, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Guadalupana Grocery and Deli impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that cigarette 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 Guadalupana Grocery and Deli.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 27, 2014, CTP served the complaint on Respondent Guadalupana Grocery and Deli 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 Guadalupana Grocery and Deli 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 11:13 a.m. on April 21, 2013, at Respondent's business establishment, 1205 River Avenue, Lakewood, New Jersey 08701, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box 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 May 9, 2013, CTP informed Respondent of the inspector's April 21, 2013 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 1:33 p.m. on September 8, 2013, at Respondent's business establishment, 1205 River Avenue, Lakewood, New Jersey 08701, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro 100's cigarettes to a person younger than 18 years of age. The inspectors 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 Guadalupana Grocery and Deli'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. pt. 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.

