

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2012-H-0612),

Complainant,

v.

Manuel A. Fernandez d/b/a Fernandez Grocery

Docket No. C-12-870

Decision No. CR2594

Date: August 17, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving a complaint on Respondent, Manuel Fernandez d/b/a Fernandez Grocery (Fernandez Grocery), at 1101 Lindley Avenue, Philadelphia, Pennsylvania 19141, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Rodriguez Grocery impermissibly sold tobacco products to a minor and failed to verify the age of a person purchasing tobacco products, violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, 21 C.F.R. Part 1140, and seeks a \$500 civil money penalty.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on June 22, 2012, CTP served the complaint on Respondent Fernandez Grocery 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 Fernandez Grocery has not filed an answer within the time prescribed. 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, 1101 Lindley Avenue, Philadelphia, Pennsylvania, on August 9, 2011, an FDA-commissioned inspector observed the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age;
- At Respondent's business establishment, 1101 Lindley Avenue, Philadelphia, Pennsylvania, on August 9, 2011, an FDA-commissioned inspector observed staff's failure to verify prior to sale, by means of photo identification containing the bearer's birth date, the age of a person purchasing tobacco products;
- In a warning letter dated October 27, 2011, the CTP informed Respondent Fernandez Grocery of the inspector's August 9, 2011 observations, and that such actions violate federal law, 21 C.F.R. §§ 1140.14(a) and 1140.14(b). The letter further warned that Fernandez Grocery's failure to correct its violation[s] could result in a civil money penalty or other regulatory action;
- At approximately 2:13 p.m. on March 30, 2012, at Respondent's business establishment, 1101 Lindley Avenue, Philadelphia, Pennsylvania, an FDA-commissioned inspector observed the sale of Newport Non-Menthol Box cigarettes to a person younger than 18 years of age;
- At approximately 2:13 p.m. on March 30, 2012, at Respondent's business establishment, 1101 Lindley Avenue, Philadelphia, Pennsylvania, an FDA-commissioned inspector observed staff's failure to verify prior to sale, by means of photo identification containing the bearer's birth date, the age of a person purchasing tobacco products.

These facts establish Respondent Fernandez Grocery'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); 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). 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. 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 person purchasing the tobacco product is younger than 18 years of age.

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

