Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-0763)

Complainant

v.

MKA Fuel Inc. d/b/a Citgo,

Respondent.

Docket No. C-14-1270

Decision No. CR3323

Date: August 8, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, MKA Fuel Inc. d/b/a Citgo, at 2801 South Schaefer Highway, Detroit, Michigan 48217, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Citgo unlawfully sold cigarettes to minors and, on two occasions, failed to verify the age of a tobacco purchaser by means of photographic identification containing the bearer's date of birth, 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 Citgo.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on June 12, 2014, CTP served the complaint on Respondent Citgo 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 Citgo 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 Respondent's business establishment, 2801 South Schaefer Highway, Detroit, Michigan 48217, on March 9, 2013, at approximately 9:35 AM, an FDA-commissioned inspector observed Respondent's staff sell a package of Newport Box cigarettes to a person younger than 18 years of age. The inspectors also noted that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older;
- In a warning letter issued on June 27, 2013, CTP informed Respondent of the inspector's observations from March 9, 2013, 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 violation, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 2801 South Schaefer Highway, Detroit, Michigan 48217, on November 23, 2013, at approximately 3:34 PM, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspectors also noted that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older

These facts establish Respondent'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 or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photo identification containing the bearer's date of birth, that no cigarette or smokeless tobacco purchaser is 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 MKA Fuel Inc. d/b/a Citgo. 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