# **Department of Health and Human Services**

### DEPARTMENTAL APPEALS BOARD

#### **Civil Remedies Division**

Center for Tobacco Products, (FDA No. FDA-2014-H-1843)

Complainant,

v.

Local Fuel, Inc. / Jayprakash Sata d/b/a Citgo,

Respondent.

Docket No. C-15-314

Decision No. CR3574

Date: January 13, 2015

### INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Local Fuel, Inc. / Jayprakash Sata, d/b/a Citgo, 5605 Livernois Avenue, Detroit, Michigan 48210, 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 failed to verify that the 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, Cigarettes and Smokeless Tobacco, 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 November 13, 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 approximately 7:28 p.m. on April 27, 2013, at Respondent's business establishment, 5605 Livernois Avenue, Detroit, Michigan 48210, an FDA-commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes. 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;
- In a warning letter dated May 9, 2013, CTP informed Respondent of the inspector's April 27, 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 4:00 p.m. on May 10, 2014, at Respondent's business establishment, 5605 Livernois Avenue, Detroit, Michigan 48210, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes. 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 Citgo'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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

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 Local Fuel, Inc. / Jayprakash Sata, 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