Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-2191)

Complainant,

v.

Trina Fletcher Lemm d/b/a Jessie's Jiffy Stop,

Respondent.

Docket No. C-15-670

Decision No. CR3652

Date: February 13, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Trina Fletcher Lemm d/b/a Jessie's Jiffy Stop, at 29596 South Montpelier Road, Albany, Louisiana 70711¹ and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Jessie's Jiffy Stop unlawfully sold cigarettes to minors, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and

¹ My office sent an Initial Order Establishing Procedures to the Respondent at this address indicating that it must respond to CTP's complaint within 30 days of service of the complaint or the Administrative Law Judge assigned to this case would decide this matter without a hearing. The United States Postal Service returned the mailing as undeliverable. However, CTP filed a proof of service of their complaint and cover letter which informed the Respondent that it must take action within 30 days after delivery of the complaint. Therefore, the Respondent had notice of the complaint and that it is subject to default.

its implementing regulations, 21 C.F.R. pt. 1140. CTP seeks to impose a \$250 civil money penalty against Respondent Jessie's Jiffy Stop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 17, 2014, CTP served the complaint on Respondent Jessie's Jiffy Stop 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 Jessie's Jiffy Stop 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, 29596 South Montpelier Road, Albany, Louisiana 70711, on January 11, 2014, at approximately 12:27 PM, an FDAcommissioned inspector observed Respondent's staff sell a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age;
- In a warning letter issued on April 3, 2014, CTP informed Respondent of the inspector's observation from January 11, 2014, and that such an action violates federal law, 21 C.F.R. § 1140.14(a). 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, 29596 South Montpelier Road, Albany, Louisiana 70711, on June 21, 2014, at approximately 12:20 PM, FDAcommissioned inspectors documented Respondent's staff selling a package of Marlboro Gold Pack 100's cigarettes to a person younger than 18 years of age.

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 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. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 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.

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

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Trina Fletcher Lemm d/b/a Jessie's Jiffy Stop. 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