

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1259)

Complainant,

v.

Leaf Cafe, LLC / Pierre Estopey and Tim May
d/b/a Leaf Cafe,

Respondent.

Docket No. C-14-1783

Decision No. CR3441

Date: October 31, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Leaf Cafe, LLC / Pierre Estopey and Tim May d/b/a Leaf Cafe, at 15 Beaufain Street, Charleston, South Carolina 29401, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Leaf Cafe sold regulated tobacco products through a vending machine in a non-exempt facility, unlawfully sold cigarettes to a minor, and failed to verify, by means of photo identification containing a date of birth, that the cigarette purchaser was 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 \$2,000 civil money penalty against Respondent Leaf Cafe.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 2, 2014, CTP served the complaint on Respondent Leaf Cafe 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 Leaf Cafe 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 an unspecified time on September 30, 2013, at Respondent's business establishment, at 15 Beaufain Street, Charleston, South Carolina 29401, an FDA-commissioned inspector observed the use of a vending machine in a non-exempt facility. During the inspection the owner of Leaf Café told the inspector that minors were allowed to enter the establishment before 10:00 p.m.;
- In a warning letter dated November 21, 2013, CTP informed Respondent of the inspector's September 30, 2013 observation, and that such actions violate federal law, 21 C.F.R. § 1140.14(c). 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 6:26 p.m. on January 31, 2014, at Respondent's business establishment, at 15 Beaufain Street, Charleston, South Carolina 29401, FDA-commissioned inspectors observed a person younger than 18 years of age enter the establishment and purchase a package of Parliament cigarettes from a vending machine. 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 Leaf Cafe'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). 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(c) a retailer may sell cigarettes or smokeless tobacco only in a direct, face- to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine or a self-service display). Lastly, under 21 C.F.R. § 1140.16(c), self-service displays of cigarettes and smokeless

tobacco are a prohibited method of sale, except where no minors are present or permitted to enter the establishment at any time. 21 C.F.R. § 1140.16(c)(2)(ii).
A \$2,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Leaf Cafe, LLC / Pierre Estopey and Tim May d/b/a Leaf Cafe. 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