

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

STEBPC, LLC
d/b/a Blue Plate Cafe,

Respondent.

Docket No. C-15-695
FDA Docket No. FDA-2014-H-2218

Decision No. CR3707

Date: March 11, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, STEBPC, LLC d/b/a Blue Plate Cafe that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$2,000.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly utilized a vending machine to sell regulated tobacco products in a non-exempt facility, and offered tobacco products for sale using false or misleading advertising,

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 (2013). CTP seeks a civil money penalty of \$2,000.

On January 14, 2015, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Blue Plate Cafe, an establishment that sells tobacco products and is located at 180 Woodford Avenue, Plainville, Connecticut 06062. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-13-963, FDA Docket Number FDA-2013-H-0802, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. Specifically, on April 25, 2012, and December 17, 2012 the Respondent utilized a vending machine in a non-exempt facility. On April 25, 2012 and on December 17, 2012, Respondent offered tobacco products for sale through a vending machine using false or misleading advertising. Complaint ¶ 10; July 5, 2013 Complaint ¶ 1, 10.
- The previous action concluded when, on August 27, 2013, an Administrative Law Judge issued an Initial Decision and Default Judgment finding Respondent liable for the violations. That Initial Decision became final and binding on the parties on September 26, 2013. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment conducted on June 5, 2014 at an unspecified time, FDA-commissioned inspectors documented a violation for selling misbranded tobacco products through a vending machine.

Specifically the inspectors noted the establishment has a vending machine with “selection buttons “[s]election buttons marked ‘Marlboro Light’ and ‘Marlboro Light 100s.’” However, the “cigarettes stocked to correspond to with the ‘Marlboro Light’ and ‘Marlboro Light 100s’ button are not labeled as such.”
Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). A tobacco product is also misbranded under section 903 of the Act if its labeling is false or misleading in any particular or if it is offered for sale and its advertising is false or misleading in any particular. 21 U.S.C. § 387c(a)(1) and (a)(7)(A). 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 require retailers to sell cigarettes or smokeless tobacco exclusively in a direct, face-to-face exchange without the assistance of any mechanical device in a facility that does not ensure that no person younger than 18 years of age is present or permitted to enter, at any time. 21 C.F.R. § 1140.14(c).

Taking the above alleged facts as true, on April 23, 2012 and again on December 17, 2012, Respondent impermissibly maintained a vending machine in a facility that allows minors to enter, in violation of 21 C.F.R. § 1140.14(c). On those same dates as well as on June 5, 2014, Respondent violated the prohibition against offering tobacco products for sale using false or misleading advertising, 21 U.S.C. § 387c, when it sold cigarette packages that did not correspond to their labels on the vending machine and contained the labels “light.”

CTP has requested a civil fine of \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil penalty of \$2,000 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge