

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-13-963
FDA Docket No. FDA-2013-H-0802

Decision No. CR2904

Date: August 27, 2013

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, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$750. Respondent did not timely 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 order that Respondent pay a civil money penalty in the amount of \$750.

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 used a vending machine to sell regulated tobacco products in a non-exempt facility and sold misbranded tobacco products through the vending machine, thereby violating the

Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$750.

On July 8, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), 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 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 by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not file an answer within the time provided by regulation.

I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically:

- Respondent owns Blue Plate Cafe, a business that sells tobacco products and is located at 180 Woodford Avenue, Plainville, Connecticut 06062. Complaint ¶ 2.
- On April 25, 2012, an FDA-commissioned inspector observed a violation of the regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Specifically, the inspector observed a violation of 21 C.F.R. § 1140.14(c) because Respondent "us[ed] a vending machine in a non-exempt facility." Complaint ¶ 10.
- On August 23, 2012, CTP issued a warning letter to Respondent detailing the inspector's observations from April 25, 2012. The letter described the violation and advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violation. The letter also informed Respondent that the inspector observed another potential violation of the Act. Specifically, the establishment's vending machine contained a selection button marked "Marlboro Lights." The letter explained that under the Act, a package of cigarettes is deemed misbranded if the package dispensed from a vending machine does not match the selection button on

the machine. Finally, the letter warned Respondent that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.

- The FDA did not receive a response to the warning letter, but the delivery records show that "STEWART" received the warning letter on August 24, 2012. Complaint ¶ 11.
- During a two-part inspection conducted on December 3, 2012, and December 17, 2012, FDA commissioned inspectors documented additional violations at Respondent's establishment. The inspectors observed a violation of 21 C.F.R. § 1140.14(c) because "the establishment ha[d] a vending machine that s[old] cigarettes and [Respondent] permit[ted] minors to enter [the establishment] when accompanied by an adult." In addition, the inspectors observed a violation of section 301 of the Act (21 U.S.C. § 331) when they noted that Respondent offered "misbranded tobacco products [for sale] through a vending machine." Specifically, the establishment's vending machine had "selection buttons marked 'Marlboro Lights[,] [but] [t]he cigarettes stocked to correspond with the 'Marlboro Lights' buttons [were] 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 sold or distributed 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 regulations require a retailer to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine). 21 C.F.R. § 1140.14(c). However, vending machines are permitted in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(ii).

Here, FDA-commissioned inspectors observed Respondent use a vending machine to sell cigarettes or smokeless tobacco while inspecting the establishment on April 25, 2012, and during a two-part inspection on December 3, 2012 and December 17, 2012. By using a vending machine to conduct these sales, Respondent violated the regulation that requires retailers to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device. 21 C.F.R. § 1140.14(c). On those dates, Respondent's establishment was not exempt from this requirement because minors were permitted to enter the establishment if accompanied by an adult. *See* 21

C.F.R. § 1140.16(c)(ii). Also, during the two-part inspection on December 3, 2012, and December 17, 2012, the inspectors noted that Respondent's vending machine contained a cigarette selection button marked "Marlboro Lights" that did not dispense "Marlboro Lights" cigarettes. Therefore, Respondent's vending machine offered a tobacco product for sale using false or misleading advertising on the selection button, in violation of section 301 of the Act. 21 U.S.C. § 331(k); *see also* 21 U.S.C. § 387c(a)(7)(A). Respondent's actions constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$250 for the second violation of 21 C.F.R. Part 1140 within a twelve-month period. 21 C.F.R. § 17.2. CTP has requested a civil money penalty in that amount for the violations of 21 C.F.R. Part 1140. However, civil money penalties for violations of section 301 of the Act are not governed by the 21 C.F.R. § 17.2. Retailers who have committed violations of section 301 of the Act (21 U.S.C. § 331) that relate to tobacco products may incur a civil money penalty up to \$15,000 for each such violation, not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding. 21 U.S.C. § 333(f)(9)(A). CTP has requested a civil money penalty of \$500 for the violation of section 301 of the Act (21 U.S.C. § 331).^{1 2} I conclude that a civil money penalty of \$750 is permissible under the Act and enter a default judgment against Respondent with an order that Respondent pay a civil money penalty in that amount.

/s/

Steven T. Kessel
Administrative Law Judge

¹ In paragraph one of the Complaint, CTP alleges that Respondent was "[s]elling misbranded tobacco products through a vending machine, in violation of Section 301 of the Act (21 U.S.C. § 387c)." However, section 301 of the Act is codified under 21 U.S.C. § 331. Throughout the rest of the Complaint, CTP cites the violation for a sale of misbranded tobacco products as a violation of section 903 of the Act (21 U.S.C. § 387c). The text of 21 U.S.C. § 387c lists the ways in which "[a] tobacco product shall be deemed misbranded," while 21 U.S.C. § 331 prohibits certain acts and "the causing thereof." Therefore, I conclude that CTP meant to continue to cite that Respondent violated section 301 of the Act (21 U.S.C. § 331) throughout the Complaint, not section 903 of the Act (21 U.S.C. § 387c).

² In paragraph fourteen of the Complaint, CTP requests a "\$500 [penalty] for two violations of section 903 [of the Act] . . ." However, based on the facts alleged in the Complaint, I find only one violation of section 301 of the Act has been proven.