

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. 2017-H-1902)

Complainant

v.

Bursaw's Pantry, LLC
d/b/a Bursaw's Pantry,

Respondent.

Docket No. T-17-3187

Ruling No. 2018-T-1

Date: October 20, 2017

**ORDER GRANTING IN PART AND DENYING IN PART CTP'S MOTION FOR
SUMMARY DECISION AND DENYING RESPONDENT'S MOTION TO
DISMISS**

I. Background and Procedural History.

Complainant, the Center for Tobacco Products (CTP), began this matter by serving an administrative complaint (Complaint) on Respondent, Bursaw's Pantry, LLC d/b/a Bursaw's Pantry, 3020 Lafayette Road, Portsmouth, New Hampshire 03801, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

The complaint alleges that Respondent impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the 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, 21 C.F.R. pt. 1140. As provided for in 21 C.F.R. §§ 17.5 and 17.7, on April 6, 2017, CTP properly served its Complaint on Respondent.

In its timely filed Answer, Respondent did not deny the substance of the violations alleged in the Complaint, but instead denied only the number of violations, arguing that CTP had improperly counted the violations against Respondent. Answer at 1. On May 11, 2017, I issued an order acknowledging receipt of Respondent's Answer and establishing procedural deadlines for this case.

On August 17, 2017, Respondent submitted a Motion to Dismiss (MTD) in which it again argued that CTP's Complaint alleged only two instances of violations against it, based on the dates of the inspections relied upon in the Complaint. MTD at 2. Respondent also argued dismissal of CTP's Complaint was appropriate because it should not be held liable for the actions of its employees. *Id.* at 1. Finally, Respondent argued dismissal was appropriate in this case because it had ceased operations as a purveyor of tobacco as of November 30, 2016. *Id.* at 2.

On September 5, 2017, CTP filed a Motion for Summary Decision (MSD) on the grounds that Respondent had admitted the alleged violations in the Complaint and only disputed the amount of the civil money penalty sought by CTP, obviating the need for further proceedings. MSD at 2. CTP requested that I enter summary decision and impose a \$550 civil money penalty against Respondent. *Id.*

CTP also filed a response on that date in opposition to Respondent's Motion to Dismiss. As of the date of this Order, Respondent has not filed a response to the Motion for Summary Decision.

II. CTP's Motion for Summary Decision Is Granted As to Liability.

I have the authority to grant a motion for a summary decision if "the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b). Here, the material facts in this case are undisputed. In its Answer, Respondent contested only the appropriateness of the penalty requested by CTP. Answer at 1-2. Its failure to deny the other allegations in the Complaint amounts to admissions of those allegations. 21 C.F.R. § 17.9(b)(1) ("[A]llegations not specifically denied in an answer are deemed admitted.").

Upon deeming those allegations which Respondent has failed to deny as admissions, I find Respondent has admitted to both selling tobacco products to minors and failing to request photographic identification. Specifically:

- Respondent owns Bursaw's Pantry, an establishment that sells tobacco products and is located at 3020 Lafayette Road, Portsmouth, New Hampshire 03801. Complaint ¶¶ 7-8.
- During an inspection of Respondent's establishment on November 5, 2015, at approximately 6:15 PM, an FDA-commissioned inspector documented that "a

person younger than 18 years of age was able to purchase a package of L&M cigarettes . . . [.]” Complaint ¶ 11.

- On January 21, 2016, CTP issued a Warning Letter to Respondent regarding the inspector’s documented violation from November 5, 2015. The letter explained that the documented violation constituted a violation of regulation, and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 12.
- During a subsequent inspection of Respondent’s establishment on October 25, 2016, at approximately 6:02 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 9.

These facts, as admitted by Respondent, establish its liability under the Act, and that CTP is entitled to partial summary decision as a matter of law. 21 C.F.R. § 17.17(b). 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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1),¹ no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser’s date of birth, that no tobacco product purchasers are younger than 18 years of age.

The only allegation in the Complaint that Respondent contests is that three violations took place on October 25, 2016 and November 5, 2016; Respondent asserts that each inspection date should be counted as one violation. Answer at 2. This argument is erroneous as a matter of law, and thus does not require further fact-finding to adjudicate. CTP’s method of counting each regulatory violation separately is based on a reasonable and permissible interpretation of the Federal Food, Drug, and Cosmetic Act (“FDCA”) and implementing regulations. The Departmental Appeals Board has specifically considered the violation-counting theory espoused by Respondent and rejected it. *See*

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

Orton Motor Company, d/b/a Orton's Bagley, DAB No. 2717 (2016). I therefore reject Respondent's contention and find, as a matter of law, that CTP's method of counting violations, and subsequent maximum penalty calculation, were appropriate in this case.

Respondent also asserted in its Answer that it cannot reasonably be held liable for the actions of its employees. This argument is without merit, but is addressed more thoroughly below as it pertains to Respondent's Motion to Dismiss.

As for the civil money penalty requested by CTP, I find it premature to grant the maximum amount allowable under the regulations, as Respondent has not yet been given the opportunity to present evidence to contest the appropriateness of the amount, including any mitigating factors I should consider. I therefore find that granting summary decision in its entirety to CTP would be inappropriate.

Instead, partial summary decision is appropriate here because the facts establishing Respondent's liability under the Act are undisputed. However, I must still determine the amount of the civil money penalty to be imposed, which I will further address below.

CTP's Motion for Summary Decision is hereby **GRANTED** as to liability and **DENIED** as to the penalty amount requested by CTP.

III. Respondent's Motion to Dismiss Is Denied.

Respondent has failed to establish any grounds to support its Motion to Dismiss. As noted above, Respondent's argument that the number of violations forming the basis of CTP's Complaint must be limited to the number of inspections fails as a matter of established law.

Similarly, Respondent's argument that it should not be held liable for the actions of its employees is without merit. See TOH, Inc. d/b/a Ridgeville Service Center, DAB CR4096 (2015) ("A corporation must necessarily bear responsibility for the acts of its employees taken on the corporation's behalf, even when those acts are in violation of corporate policy."). Respondent does not allege that its employees were acting outside of the scope of their employment when the violations occurred.

Finally, Respondent asserted in its Answer and in its Motion to Dismiss that it had ceased operations as of November 2016, the implication being that the action undertaken by CTP and any resulting penalty are ultimately moot. See Answer at 3; MTD at 2. Even if true, Respondent's claim that it no longer operates a retail store selling tobacco products does not amount to a defense. In its Answer, Respondent did not deny it owned and operated the retail store that impermissibly sold tobacco products to minors and failed to verify identification on the dates alleged in the Complaint. Respondent therefore remains liable for the conduct that took place while it operated the business in question.

For the reasons discussed above, Respondent's Motion to Dismiss is **DENIED**.

IV. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Bursaw's Pantry is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP seeks to impose the maximum penalty amount of \$550.

I find that Respondent has committed three violations within a twenty-four month period. I must now determine the appropriate penalty amount to impose. When determining the amount of a civil money penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 333(f)(5)(B).

I will now give the parties the opportunity to make written arguments and present evidence on the appropriateness of the amount of civil money penalty. Respondent should submit evidence or arguments concerning the factors I have outlined that it believes support a lower penalty amount. CTP may similarly submit evidence or arguments supporting a higher penalty amount. Each party must simultaneously submit its arguments and evidence to my office and to the other party.

CTP's written argument and supporting evidence, if any, are due **November 13, 2017**. Respondent's written argument and supporting evidence are due **December 1, 2017**. I will not accept response briefs from either party.

I strongly encourage the parties to contact each other and discuss settlement prior to the submission of arguments as to the penalty amount to be imposed by me.

SO ORDERED.

/s/
Bill Thomas
Administrative Law Judge