

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

Center for Tobacco Products,
(FDA No. FDA-2017-H-1266)

Complainant

v.

Smoky's Cigars, Inc.
d/b/a Smoky's Cigar Lounge / Smoky's Fine Cigars,

Respondent.

Docket No. T-17-2596

Decision No. TB2271

Date: December 11, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Smoky's Cigars, Inc. d/b/a Smoky's Cigar Lounge / Smoky's Fine Cigars, at 42919 Woodward Avenue, Bloomfield Hills, Michigan 48304, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Smoky's Cigar Lounge / Smoky's Fine Cigars 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.

The complaint likewise alleges that Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and has now committed a total of seven violations of 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, within a forty-eight month period. Therefore, CTP seeks to impose an \$11,002 civil money penalty against Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars. I previously found Respondent liable for seven violations of FDA tobacco regulations in a

forty-eight month period, and hereby enter judgment in the amount of \$11,002 against Respondent, Smoky's Cigars, Inc., d/b/a Smoky's Cigar Lounge / Smoky's Fine Cigars.

Background and Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on March 16, 2017, CTP served the complaint on Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars by United Parcel Service. On April 17, 2017, Respondent timely filed an Answer ("Respondent's Answer").

In its Answer, Respondent admitted all of the allegations in the Complaint. Respondent's Answer at 1.

Respondent raised three "affirmative defenses" with regard to the issue of penalty: (1) the two brothers who run Smoky's Cigar Lounge / Smoky's Fine Cigars, have a practice of asking tobacco products purchasers, who appear to be under the age of thirty (30), for their identification; (2) the brothers have placed signs all through the store informing patrons about the identification requirement, and that they placed lettering on the front door that informs patrons that they "must be over 18 to enter the store," and (3) Respondent stated that it is "giving every effort that this must never happen again." Respondent's Answer at 2. With respect to the appropriateness of the civil money penalty that the CTP seeks, Respondent states that it is exorbitant and would impair the brothers' ability "to make a living." *Id.*

i. CTP's Motion for Partial Summary Decision

On May 25, 2017, the parties filed a joint status report indicating that the "parties have been unable to reach a settlement in this case and intend to proceed to a hearing." On that same day, CTP filed a Motion for Partial Summary Decision ("Motion") on the ground that Respondent has admitted the alleged violations in the Complaint, and only disputes the civil money penalty amount. Therefore, CTP "requests that [I] enter summary decision in its favor on the question of liability for the violations alleged in the Complaint, and allow the matter to proceed to hearing on the question of civil money penalty amount." Motion at 2. In a May 30, 2017 letter written at my direction, I allowed Respondent until June 26, 2017, to file a Response to CTP's Motion. Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars did not file a response within the time prescribed. On July 12, 2017, CTP filed a Motion to Extend Deadlines.

On July 19, 2017, I (1) granted CTP's Motion for a Partial Summary Decision on the issue of Respondent's liability for the violations alleged in the Complaint; (2) gave the parties "an opportunity to develop the penalty issue, and submit written arguments and any corresponding evidence[]" on or before the exchange dates; and (3) extended all deadlines by sixty (60) days. *See* July 19, 2017 Order, Docket No. 12. I also informed

the parties that I will render a decision on the record after I receive all evidence and arguments on the amount of the civil money penalty. *Id.* at 4-5.

ii. Finding on the Issue of Respondent's Liability

In my July 19, 2017 Order, I noted that Respondent had previously admitted liable for five violations namely: (1) use of self-service display in a non-exempt facility, and distribution of free samples on June 11, 2013; (2) sale to a minor on July 9, 2014; (3) use of a self-service display in a non-exempt facility on July 16, 2014; (4) sale to a minor on February 6, 2015; and (5) failure to verify the age of a purchaser tobacco by means of photographic identification on February 6, 2015. *See* July 19, 2017 Order, Docket No. 12 at 3, note 2. I also found Respondent liable for two additional violations of FDA tobacco regulations: selling tobacco products to a minor and failure to verify the age of a purchaser tobacco by means of photographic identification, both on September 18, 2016. Accordingly, I found Respondent liable for seven violations of FDA tobacco regulations in a forty-eight month period. *See id.* at 3-4.

Decision on the Record

Pursuant to 21 C.F.R. § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. On September 14, 2017, CTP filed its informal brief ("Informal Brief of Complainant") and three proposed exhibits (CTP Exs. 1-3) in its exchange. CTP did not propose any witnesses. Respondent did not object to any of CTP's proposed exhibits. Therefore, I admit CTP Exs. 1-3 into the record.

Respondent did not file any proposed exhibits or identify any proposed witnesses. I note that Respondent did not file an exchange or any supplemental briefs on the penalty issue within the allotted time. I further note that the only document or response that Respondent has filed in this case is its Answer. Because neither party has proposed witnesses or requested to cross-examine an opposing party's witness, I consider the evidentiary record to be complete.

My July 19, 2017 Order, finding Respondent liable for the violations alleged in the Complaint, is incorporated herein. Respondent committed seven violations of the Act and its implementing regulations within a forty-eight month period. As a result of my liability determination, I find that a final decision on the record with regarding the penalty issue is appropriate. I will now decide the penalty issue on the basis of the written record.

Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars 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 \$11,002, against Respondent for seven violations of the Act and its implementing regulations within a forty-eight month period. Under 21 C.F.R. § 17.2, an \$11,002 civil money penalty is permissible for seven violations of the regulations found at 21 C.F.R. pt. 1140.

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. *Nature, Circumstances, Extent and Gravity of the Violations*

I have found that Respondent committed a total of seven repeated violations of FDA tobacco regulations within a period a 48-month period. *See* July 19, 2017 Order. Respondent’s repeated inability to comply with federal tobacco regulations raises a serious concern for the wellbeing of minors. CTP correctly states that “[a]ll of Respondent’s violations are serious in nature as they contravene FDA’s efforts to protect minors from the multitude of adverse health effects associated with tobacco use.” Informal Brief of Complainant at 4. Despite Respondent’s prior civil money penalty (“CMP”) actions and repeated warnings from the FDA that “additional violations would result in more serious consequences,” Respondent still sold tobacco products to a minor and failed to verify the age of the minor on September 18, 2016. *See* Complaint ¶¶ 1, 8, 10-11; *see also* Informal Brief of Complainant at 4. Accordingly, I find that a civil money penalty is necessary to deter Respondent from future violations of FDA tobacco regulations.

ii. *Respondent’s Ability to Pay*

CTP is seeking an \$11,002 civil money penalty against Respondent Smoky’s Cigar Lounge / Smoky’s Fine Cigars. In its Answer, Respondent states that as a “family business just trying to make a living [it] cannot afford these fines it would hurt us very bad.” Respondent’s Answer at 2. Respondent provided no other evidence of its inability to pay, nor of the financial hardship that would be incurred if I impose the penalty. As noted earlier, I afforded the parties an opportunity to supplement the record by briefing the penalty issue but Respondent did not do so. Without more evidence, I have no way to evaluate whether or not the CTP’s proposed penalty would impair the Respondent’ ability “to make a living.” *See id.*

iii. *Effect on Ability to do Business*

Besides stating in its Answer that the penalty is too high, among other considerations, Respondent has not presented any evidence about the effect of an \$11,002 civil money penalty on its ability to conduct its business. CTP argues that “[an] \$11,002 civil money penalty will not affect the Respondent’s ability to do business [because] respondent may continue to sell tobacco products and other products at the establishment.” Informal

Brief of Complainant at 6. Without evidence to the contrary, I find that the proposed civil money penalty will not have a substantial effect on Respondent's ability to do business.

iv. *History of Prior Violations*

It is undisputed that Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars is a repeated violator of FDA's tobacco regulations prohibiting the sale of tobacco products to minors. Respondent has been the subject of two prior CMP actions. *See* CRD Docket C-15-2899, FDA Docket FDA-2015-H-2128 (Most Recent CMP Action); *see also* CRD Docket C-15-433, FDA Docket FDA-2014-H-1962.¹ This is the third civil money penalty action brought against Respondent within the past forty-eight months for violations of the Act and its implementing regulations, bringing the total number of violations to seven. *See* Complaint ¶¶ 1, 10-11. Specifically, Respondent's violation count includes three sales to a minor in violation of 21 C.F.R. § 1140.14(a), two failures to verify identification in violation of 21 C.F.R. § 1140.14(b)(1), two uses of a self-service display in a non-exempt facility in violation of 21 C.F.R. § 1140.16(c), and one distribution of free samples in violation of 21 C.F.R. § 1140.16(d)(1).²

v. *Degree of Culpability*

The facts of this case are not in dispute. Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars admitted to all of the violations in its Answer. *See* Answer at 2. CTP asserts that "following the first violation, [it] reminded Respondent about its responsibilities under the law, directed Respondent to resources to help ensure compliance with the law, and notified Respondent that a future violation could result in a civil money penalty." Informal Brief of Complainant at 7; *see* Warning Letter, CTP Ex. 1. It is troubling that after two prior CMPs and a warning letter from the FDA, Respondent has failed to correct its violations and comply with the FDA tobacco regulations. Based on my finding that Respondent committed the most recent violations in the current complaint, I hold it fully culpable for all seven repeated violations of the Act and its implementing regulations.

¹ For the first CMP Action Respondent's business name was Mary Jo Essa, Paul Essa, and Peter Essa d/b/a Smoky's Cigar Lounge / Smoky's Fine Cigars. *See* CRD Docket C-15-433, FDA Docket FDA-2014-H-1962

² CTP documented two violations on June 11, 2013 (use of a self-service display in a non-exempt facility and distribution of free samples), one on July 9, 2014 (sale to a minor), one on July 16, 2014 (use of a self-service display in a non-exempt facility), two on February 6, 2015 (sale to a minor and failure to verify through photographic identification), and two on September 18, 2016 (sale to a minor and failure to verify through photographic identification). In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

vi. *Additional Mitigating Factors*

Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars has taken responsibility for its conduct. Respondent stated "I understand how serious this is and as a family we are committed to this never happening again." Answer at 2. While I commend Respondent for accepting responsibility for the violations, expressing remorse, and communicating its efforts to ensure "that this must never happen again," I do not find any mitigating factors. See Answer at 2. Respondent asserts that it placed signs all through the store informing patrons about the identification requirement, and that they placed lettering on the front door that informs patrons that they "must be over 18 to enter the store." *Id.* However, Respondent has not provided any evidence that it has implemented new policies for its employees about when to verify the age of tobacco product purchasers. Because this is Respondent's third CMP action, and Respondent has had ample opportunity to correct its violations and come into compliance, I find that a civil money penalty of \$11,002 is appropriate.

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$11,002 against Respondent Smoky's Cigars, Inc. d/b/a Smoky's Cigar Lounge / Smoky's Fine Cigars, for seven violations of 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, within a forty-eight month period. 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