

**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

Ruling No. 2017-T-1

Date: July 19, 2017

**ORDER GRANTING COMPLAINANT'S MOTIONS FOR PARTIAL SUMMARY  
DECISION AND EXTENSION OF EXCHANGE DEADLINES**

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, 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. 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.*

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. In that motion, CTP requested that “any deadlines, including the . . . deadline for filing CTP’s Pre-Hearing Exchange, be extended thirty (30) days . . . .”

## **II. Discussion**

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). The material facts in this case are undisputed. Specifically:

- On June 24, 2015, CTP initiated the Most Recent Civil Money Penalty Action (“Most Recent CMP Action”),<sup>1</sup> CRD Docket Number C-15-2899, FDA Docket Number FDA-2015-H-2128, against Respondent for five<sup>2</sup> violations of 21 C.F.R. pt. 1140 within a thirty-six month period. CTP alleged those violations to have occurred at Respondent’s business establishment, 42919 Woodward Avenue, Bloomfield Hills, Michigan 48304, on June 11, 2013, July 9, 2014, July 16, 2014, and February 6, 2015. Complaint ¶ 10.
- The Most Recent CMP Action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, “Respondent expressly waived its right to contest such violations in subsequent actions.” Complaint ¶ 11.
- At approximately 1:16 p.m. on September 18, 2016, at Respondent’s business establishment, 42919 Woodward Avenue, Bloomfield Hills, Michigan 48304, an FDA-commissioned inspector documented Respondent’s staff selling a package of Marlboro Silver Pack cigarettes to a person younger than 18 years of age. The inspector 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. Complaint ¶ 8.

These facts establish Respondent Smoky's Cigar Lounge / Smoky's Fine Cigars’s liability under the Act and 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).

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<sup>1</sup> CTP referred to a first civil money penalty action, FDA Docket FDA-2014-H-1962, CRD Docket C-15-433. *See* Complaint ¶ 10d. It appears that CTP included the violations from that action in the Most Recent Civil Money Penalty Action.

<sup>2</sup> Two violations were documented on July 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), and two on February 6, 2015 (sale to a minor and failure to verify though 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.

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)<sup>3</sup>, 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. Under 21 C.F.R. § 1140.16(c), no retailer may use a self-service display in a non-exempt facility. Under 21 C.F.R. § 1140.16(d)(1) no retailer may distribute free samples of tobacco products.

A partial summary decision is appropriate here because the facts of this case are undisputed and Respondent is liable, under the Act, for the violations as alleged in the Complaint.

### III. 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.

I find that Respondent committed seven violations of the Act and its implementing regulations within a forty-eight month period. 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). As a result of my liability determination, I find that a final decision on the record with regard to that issue is appropriate in this matter. Accordingly, I will now give the parties the opportunity to present evidence on the appropriateness of the amount of Civil Money Penalty.

### Order

CTP's Motion for a Summary Decision on the issue of Respondent's liability for the violations, as alleged in the Complaint, is hereby **GRANTED**.

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<sup>3</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

