

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-3470)

Complainant

v.

Locals Smoking Shop Inc.
d/b/a Smokin Brothers Tobacco Shop,

Respondent.

Docket No. T-17-4605

Decision No. TB2407

Date: January 31, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Locals Smoking Shop Inc. d/b/a Smokin Brothers Tobacco Shop, located at 2005 Gulf to Bay Boulevard, Clearwater, Florida 33765, for three (3) 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 twenty-four month period. Specifically, CTP alleges that Smokin Brothers Tobacco Shop violated the Act by impermissibly selling cigarettes to minors and by failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$559 civil money penalty on Respondent Smokin Brothers Tobacco Shop at 2005 Gulf to Bay Boulevard, Clearwater, Florida 33765, and by filing a copy of the complaint

with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. On July 20, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines regarding discovery and for the parties to file their pre-hearing exchanges.

On October 2, 2017, Respondent filed a "Motion for Insufficient Service of Process." Respondent's motion requested that I waive or extend the August 28, 2017 deadline to request documents set forth in the APHO in order that Respondent may request documents from CTP. On October 12, 2017, CTP filed an opposition to Respondent's motion. On October 16, 2017, I denied Respondent's motion stating that Respondent had not articulated any reasonable impediment to making its discovery requests within the time set forth in the APHO.

CTP filed its pre-hearing exchange on November 9, 2017. CTP's pre-hearing exchange included its Informal Brief of Complainant, a list of proposed witnesses and exhibits, and fourteen (14) numbered exhibits (CTP Exs. 1-14). CTP's exhibits included the declarations of two witnesses.

Respondent Smokin Brothers Tobacco Shop subsequently filed its pre-hearing exchange on November 25, 2017, which included its Informal Brief of Respondent and the declaration of one witness (R. Ex. 1). In its brief, Respondent did not deny the allegations asserted by CTP.

Having received the parties' exchanges, on November 28, 2017, I issued an order scheduling a pre-hearing conference for December 21, 2017. During the pre-hearing conference, Respondent further clarified its position that it was not contesting CTP's factual allegations.

Decision on the Record

Pursuant to 21 CFR § 17.37(b), all direct testimony of witnesses shall be admitted in the form of a written declaration. In its pre-hearing exchange, CTP submitted two witness declarations. Respondent Smokin Brothers Tobacco Shop submitted one witness declaration. At the December 21, 2017 pre-hearing conference, the parties agreed to forgo a hearing to cross-examine witnesses and agreed to proceed with a decision on the record. Therefore, I will decide this case on the basis of the written record.

Since Respondent Smokin Brothers Tobacco Shop has chosen not to contest the allegations in the Complaint, the only remaining issue is whether the amount of the civil money penalty is appropriate.

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent Smokin Brothers Tobacco Shop committed three violations of the Act and its implementing regulations within a twenty-four month period. On July 11, 2017, Smokin Brothers Tobacco Shop filed an answer to the Complaint denying CTP's allegations. *See Answer.* However, on November 25, 2017, Smokin Brothers Tobacco Shop filed an informal brief, that did not deny the allegations and argued for a lower civil money penalty. *See Informal Brief of Respondent.* At the December 21, 2017 pre-hearing conference, Respondent clarified that it was not contesting CTP's factual allegations.

CTP makes the following uncontested allegations:

- On February 22, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-2185, FDA Docket Number FDA-2017-H-0797, against Respondent for two¹ violations of 21 C.F.R. pt. 1140 within a twelve-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 2005 Gulf to Bay Boulevard, Clearwater, Florida 33765, on March 14, 2016, and August 13, 2016;
- The previous 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";
- At approximately 4:58 p.m. on March 29, 2017, at Respondent's business establishment, 2005 Gulf to Bay Boulevard, Clearwater, Florida 33765, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

CTP asserts that these allegations, as supported by documentary evidence, are sufficient to establish a basis for liability against Respondent. As Respondent Smokin Brothers Tobacco Shop has chosen to not dispute these allegations, I find that these facts establish Respondent Locals Smoking Shop Inc. d/b/a Smokin

¹ Two violations were documented on March 14, 2016, and one on August 13, 2016. 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.

Brothers Tobacco Shop's liability 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. § 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)², no retailer may sell cigarettes 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.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Smokin Brothers Tobacco Shop 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 sought to impose the maximum penalty amount, \$559, against Respondent for three violations of the Act and its implementing regulations within a twenty-four month period. Complaint ¶ 1. In its Informal Brief, CTP continues to assert that a \$559 civil money penalty is appropriate. Informal Brief of Complainant at 8.

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. § 303(f)(5)(B).

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

Respondent Smokin Brothers Tobacco Shop has failed to comply with the Act and its implementing regulations on three separate occasions, in March 2016, August 2016, and March 2017. I have found that Respondent committed three violations of selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and one violation for failing to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2). Respondent has been charged by Complainant with three of those violations in accordance with its customary practice to charge only one violation for the initial inspection, even

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

though the applicable regulations would permit charging for more than one. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature, and a civil money penalty is necessary.

ii. Respondent's Ability to Pay

CTP is seeking a \$559 civil money penalty against Respondent Smokin Brothers Tobacco Shop. Aside from Respondent labeling the civil money penalty as "excessive," there is no evidence in the record before me regarding Respondent's ability or inability to pay. Without evidence of Respondent's current financial situation, it is impossible to accurately assess Respondent's current ability to pay a civil money penalty.

iii. Effect on Ability to do Business

There is nothing in the evidentiary record that shows the effect a civil money penalty will have on Respondent Smokin Brothers Tobacco Shop's ability to do business. Respondent did not address how this penalty will affect its ability to do business. CTP argues that a "\$559 civil money penalty will not affect the respondent's ability to do business. Respondent may continue to sell tobacco products and other products at the establishment." Informal Brief of Complainant at 10. Without evidence to the contrary, I must conclude that a \$559 civil money penalty will not have a substantial effect on Respondent's ability to do business.

iv. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent Smokin Brothers Tobacco Shop within the past twelve months for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number T-17-2185, FDA Docket Number FDA-2017-H-0797, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on March 14, 2016 and August 13, 2016. On March 14, 2016, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2). Respondent settled these claims with CTP for an undisclosed penalty amount.

Including this current action, Respondent "has sold tobacco products to minors three times, in violation of 21 C.F.R. § 1140.14(a)(1), and failed to verify the identification of the purchaser of tobacco products once, in violation of 21 C.F.R. § 1140.14(a)(2)(i), within a twenty-four month period." Informal Brief of Complainant at 10. I agree with CTP that "[t]hese repeat violations show an

unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” *Id.* While Respondent has already paid an unknown amount in settlement of its previous violations, its continued inability to comply with the federal tobacco regulations calls for a penalty in this instance.

v. Degree of Culpability

While Respondent Smokin Brothers Tobacco Shop’s Answer initially denied the violations occurred, its Informal Brief “acknowledges that perhaps there was an error made while reading the date of birth on the I.D. provided at the time.” Informal Brief of Respondent at 1. Specifically, Respondent asserts that any error was based upon a “mistaken assessment” of the purchaser’s identification. *Id.* Based upon this acknowledgement, I have concluded that Respondent is liable for three violations of selling cigarettes to minors, however find that, in this instance, the possibility exists that Respondent’s violation was a good faith error.

vi. Additional Mitigating Factors

Respondent Smokin Brothers Tobacco Shop stated that it has taken steps to prevent future violations. Informal Brief of Respondent at 3. According to Respondent, it has taken several steps to ensure against future violations, including the implementation of a tobacco sales education program for its employees; the purchase of a “WE I.D.” age verification system; the removal of all signage that does not carry a health warning; the placement of signage indicating that the establishment does not sell to minors; and the purchase of an electronic identification scanner system. Informal Brief of Respondent at 3-4. Further, Respondent has stated that it “realizes the severity of this error and is making many efforts to become a responsible tobacco dealer and as such, has already invested time and money to resolve these problems.” Informal Brief of Respondent at 2. I find that these steps are significant and demonstrate that Respondent is committed to not incurring future violations.

vii. Penalty

I acknowledge that Respondent has taken responsible measures in order to prevent future violations. I further acknowledge the possibility that the violation, which occurred on March 29, 2017, was made as good faith error. Based on the foregoing reasoning, I will reduce the assessed penalty amount to \$250. I urge Respondent to take deliberate care to see that future violations do not occur.

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$250 against Respondent, Locals Smoking Shop Inc. d/b/a Smokin Brothers Tobacco Shop, for three 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 twenty-four month period.

/s/

Catherine Ravinski
Administrative Law Judge