

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-5815)

Complainant,

v.

Brookdale Liquors, Inc.
d/b/a Brookdale Liquors,

Respondent.

Docket No. T-17-6648

Decision No. TB3120

Date: September 24, 2018

INITIAL DECISION

I hereby sustain the determination of Complainant, Center for Tobacco Products (“CTP”) of the United States Food and Drug Administration (“FDA”) to impose a civil money penalty of \$5,591 against Respondent, Brookdale Liquors, Inc. d/b/a Brookdale Liquors, for five violations of federal tobacco regulations within a thirty-six month period.

I. Background

CTP began this matter by serving an administrative complaint on Respondent, Brookdale Liquors, Inc. d/b/a Brookdale Liquors, at 2519 8th Street South, Moorhead, Minnesota 56560, and by filing a copy of the complaint with the FDA’s Division of Dockets Management. CTP alleges that Brookdale Liquors impermissibly sold cigarettes or smokeless tobacco 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. CTP further alleges that Respondent Brookdale Liquors previously admitted to three violations of regulations found at 21

C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,591 civil money penalty against Respondent Brookdale Liquors.

II. Procedural History

On September 29, 2017, I issued an order granting Respondent's September 22, 2017 request for an extension of the time within which to file an answer. On October 18, 2017, Respondent timely filed an answer admitting all the allegations in the complaint. *See* Answer ¶ 1. In its answer, Respondent stated, "one of [its] employees did sell tobacco to a minor without asking for the proper identification. The employee involved was only on the job for his second day and his supervisor for the shift was busy with another customer at the time and not able to assist the trainee with the proper procedure for the sale of tobacco products." *Id.* Respondent submits that it has "always provided the proper training and materials to assist [its] employees in asking for the proper ID for all of [its] products." *Id.* ¶ 2. Respondent further submits that "[t]here is print material on how to identify fake ID's and they are all required to attend all server training courses that are offered." *Id.* Finally, Respondent asked for a reduction of the civil money penalty because Respondent has a policy of making employees responsible for "any penalty enforced due to their negligence to follow all proper procedures of the sale" *Id.* ¶ 3.

It appears that Respondent is requesting a reduction because the civil money penalty will cause its employee financial hardship. I want to clarify that CTP is seeking the civil money penalty against Respondent Brookdale Liquors, Inc. d/b/a Brookdale Liquors, only. Accordingly, any decision on liability that I render in this matter must be against Respondent only, and not Respondent's employee.

Based on Respondent's representations in its Answer, I inferred that the parties did not intend to proceed to a hearing in this case and might reach a settlement agreement. Accordingly, on October 25, 2017, I issued an Acknowledgment and Status Report Order (ASRO). In the ASRO, I gave the parties sixty days to file a joint status report notifying the court about whether the parties intend to proceed to a hearing. On December 26, 2017, CTP filed a Joint Status Report stating, "[t]he parties have been unable to reach a settlement in this case and intend to proceed to a hearing." On December 27, 2017, I issued a Pre-Hearing Order that set out the deadlines for the parties' submissions in this case, and informal briefs for the parties to complete and submit.¹

On June 18, 2018, CTP timely filed its pre-hearing exchange. CTP's exchange included an Informal Brief of Complainant ("CTP Br."), a list of proposed witnesses and exhibits, and 14 numbered exhibits ("CTP Ex. 1- Ex. 14"). CTP's exhibits included the written

¹ I note that during the course of this proceeding, I ruled on discovery matters which are no longer relevant to the disposition of the case: CTP's Motion to Compel Discovery (Docket No. 10), Motions to Extend Deadlines (Docket Nos. 11, 16), and Motion to Impose Sanctions (Docket No. 15).

direct testimony of two witnesses: Ms. Laurie Sternberg, Senior Regulatory Counsel, Office of Compliance and Enforcement, CTP, FDA (“Sternberg Declaration”, “CTP Ex. 4”), and Mr. Marc Baetsch (“Inspector Baetsch”), FDA-commissioned Inspector (“Baetsch Declaration,” “CTP Ex. 6”). On July 9, 2018, Respondent timely filed its pre-hearing exchange. Respondent’s exchange included an Informal Brief of Respondent and Sworn Statement of David Lundeen (“Lundeen Declaration”), and five numbered exhibits (“Respondent’s Ex. 1 - Ex. 5”).

Pre-Hearing Conference and Waiver of Hearing

On August 14, 2018, I held a pre-hearing conference by telephone. During the prehearing conference call, we discussed the parties’ pre-hearing exchanges in this matter. As a preliminary matter, I explained that the purpose of a hearing is to allow for the cross-examination and re-direct of any witnesses who have provided sworn testimony in exchanges. I also explained that a cross-examination was not required in this matter because Respondent already admitted all of the allegations in the Complaint, and I could admit the proposed exhibits during the conference, if the parties concurred. The parties agreed to a decision based on the documents entered into the record.

I asked the parties whether they objected to any of the proposed exhibits. Respondent did not object to CTP’s proposed exhibits marked as CTP Ex. 1 to CTP Ex. 14. CTP did not object to Respondent’s proposed exhibits marked as Respondent’s Ex. 1 to Ex. 5. In the absence of objections, I admitted the parties’ proposed exhibits into the record. I received Respondent’s brief (Lundeen Declaration) into evidence as written direct testimony. I understood that the parties submitted their final briefs in their exchange documents. The parties did not communicate any intent to supplement their briefs with additional arguments for my consideration. On that same day, I issued an Order Granting Waiver of Hearing and Admitting Exhibits. I hereby render my decision on the record.

III. Issue

Whether the civil money penalty of \$5,591 that CTP seeks to impose is a reasonable remedy.

IV. Applicable Regulations

The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). The FDA and its agency, CTP, may seek the imposition of remedies against any person who violates the Act’s requirements as they relate to the sale of tobacco products. 21 U.S.C. § 333(f)(9). Under 21 C.F.R. § 1140.14(a)(1)², no retailer may sell cigarettes or smokeless tobacco to any

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

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 cigarette or smokeless tobacco purchasers are younger than 18 years of age.

The Act establishes factors that a presiding officer must consider in determining the civil money penalty amount. The presiding officer must "take into account the nature, circumstances, extent, and gravity of the violation or 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).

V. Analysis

A. Allegations, Parties' Contentions, and Findings of Fact

After a thorough review of the evidence submitted by the parties, I find that Respondent committed five violations of the Act and its implementing regulations as alleged in the Complaint. *See generally* Complaint; CTP Br.; Answer; Lundeen Declaration. The sale of cigarettes or smokeless tobacco to an individual who is under the age of 18, and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. § 1140.14(a)(1), (a)(2)(i).

CTP alleges that Respondent committed five violations of the Act and its implementing regulations over a 36-month period. *See* Complaint at ¶ 1; *see* CTP Br. at 10. The Baetsch Declaration, CTP Ex. 6, corroborates CTP's current allegations. Specifically, CTP alleges that at approximately 9:19 p.m. on August 30, 2017, at Respondent's business establishment, 2519 8th Street South, Moorhead, Minnesota 56560, Inspector Baetsch documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age. Complaint ¶ 7; CTP Ex. 6 ¶¶ 8-9; CTP Br. 4. Inspector Baetsch 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 ¶ 7; CTP Ex. 6 ¶ 9; CTP Br. at 4. Finally, CTP alleged that in a previous civil money penalty action, Respondent admitted to three violations of the Act. Complaint ¶ 10; *see* CTP Br. at 2-3.

Respondent conceded that the five alleged violations occurred. *See* Answer ¶ 1; Lundeen Declaration at 1. Respondent submits that the August 30, 2017 violation was due to the "carelessness of its new employee, for which that employee was charged of a crime and plead guilty to, and paid a fine for, in recognition of the same." Lundeen Declaration at 3; *see also* Answer ¶ 1. Again, I note that the Court is not privy to or concerned with any criminal actions regarding said employee. The Court's jurisdiction and any judgment rendered in this matter extends to Respondent Brookdale Liquors, only.

Based on the evidence in the record, there is no dispute that Respondent committed five violations of the Act and its implementing regulations over a 36-month period. As Respondent conceded to the current and previous allegations, there is no dispute as to the material facts of the case before me. Accordingly, the only issue before me is whether the CMP of \$5,591 that CTP seeks to impose is a reasonable remedy.

B. Civil Money Penalty

After considering the factors under the applicable statute, I find that the CMP of \$5,591 that CTP seeks against Respondent, for five violations of the Act and its implementing regulations over a 36-month period, is reasonable. CTP can seek a civil money penalty from Respondent for violating the Act. 21 U.S.C. § 333(f)(9). When determining an appropriate penalty, the presiding officer shall evaluate any circumstances that mitigate or aggravate the violation referring to the factors identified in (but not limited to) the applicable statute. 21 C.F.R. § 17.34. Under the applicable statute, I must “take into account the nature, circumstances, extent, and gravity of the violation or 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).

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

I find that Respondent committed five violations of the Act with a thirty-six month period. Respondent admits that on August 30, 2017, a new employee, who was temporarily unsupervised, sold cigarettes to a minor and failed to verify by means of photographic identification containing a date of birth that the purchaser was 18 years of age or older. *See* Answer ¶ 1. I find Respondent’s repeated inability to comply with federal tobacco regulations to be serious in nature. Accordingly, I find that the civil money penalty of \$5,591 is reasonable under these circumstances.

b. Respondent’s Ability to Pay and Effect on Ability to do Business

While Respondent submits that the civil money penalty is too high for the employee whose actions caused the Complaint, Respondent has not provided any evidence that it does not have the ability to pay the \$5,591 penalty. Further, Respondent has not presented any evidence regarding the effect of the civil money penalty on its ability to do business. Respondent may continue to sell tobacco products so long as it complies with the Act’s prohibition of selling tobacco products to minors. I reiterate that Respondent and not its employee is responsible for any civil money penalty that I impose.

c. History of Prior Violations

Respondent is a repeated violator of FDA tobacco regulations prohibiting the sale of cigarettes to minors. This is the second civil money penalty action against Respondent

for violations of the Act and its implementing regulations. On February 28, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-2389, FDA Docket Number FDA-2017-H-1023, for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period.³ *See* Complaint ¶ 9; *see also* CTP Ex. 2 ¶¶ 1, 7, 9. CTP alleged that on June 12, 2015, and September 6, 2016, Respondent sold cigarettes 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. CTP Ex. 2 ¶¶ 1, 7, 9. Respondent has admitted the prior violations and paid the agreed upon penalty. Complaint ¶ 10; Lundeen Declaration at 1. While I commend Respondent for taking responsibility for its prior violations, Respondent's repeated inability to comply with FDA tobacco regulations is troubling and supports the imposition of a higher penalty.

d. Degree of Culpability

The record shows that Respondent sold cigarettes or smokeless tobacco to minors in violation of 21 C.F.R. § 1140.14(a)(1) on June 12, 2015, September 6, 2016, and August 30, 2017. The record shows that on those same dates, Respondent failed to verify the identification of the purchasers in violation of 21 C.F.R. § 1140.14(a)(2)(ii). Based on Respondent's admissions regarding the current and previous civil money penalty actions and the evidence on the record, I find Respondent fully culpable for five violations of the Act and its implementing regulations.

e. Additional Mitigating Factors

After reviewing Respondent's evidence, I do not find any mitigating factors. In requesting a lower civil money penalty, Respondent relies mainly on the fact that the infraction was due to new employee, who had not gone to server training, and was careless. Respondent implies that it should not be responsible for careless acts of its employees. However, it is Respondent's responsibility to train and supervise its employees. Furthermore, it Respondent's responsibility to establish policies that prevent unlawful sales of cigarettes, and other tobacco products to minors. Respondent submitted evidence that appears to be policies in place prior to hiring the new employee responsible for the sale of the tobacco products. *See* Respondent's Ex. 1- Ex. 3, Ex. 5. Respondent has not submitted any evidence to show it has made changes to its policies and procedures since the filing of this complaint. Respondent's Ex. 4 concerns alcohol sales policy, which is not an issue before me. This is the third inspection Respondent has failed even though it argues that the August 30, 2017 violations arise out of a single incident, it was still two violations and the third failed inspection. *See* Lundeen

³ CTP documented two violations on June 12, 2015 (sale to minor and failure to verify age of purchaser), and two on September 6, 2016 (sale to minor and failure to verify age of purchaser). 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.

