

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-3831)

Complainant

v.

HK 32216, Inc.
d/b/a 7-Eleven 32216A,

Respondent.

Docket No. T-17-737

Decision No. TB2446

Date: February 14, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, HK 32216, Inc. d/b/a 7-Eleven 32216A , located at 12902 South John Young Parkway, Orlando, Florida 32837, for two 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 twelve-month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling cigarettes to minors, on two separate occasions.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$275 civil money penalty on Respondent, at 12902 South John Young Parkway, Orlando, Florida, 32837, 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 denying the allegations in the Complaint. Answer at 2.

On January 10, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) acknowledging receipt of Respondent's Answer and establishing procedural deadlines for this case.

On June 15, 2017, CTP filed its pre-hearing exchange which included its informal brief (CTP Br.), a list of proposed witnesses, and thirty (30) exhibits (CTP Exs. 1-30). CTP's exhibits included the declarations of two witnesses, Laurie Sternberg, Senior Regulatory Counsel in CTP's Office of Compliance and Enforcement, and FDA-commissioned Inspector Shaun Griffin.

On October 5, 2017, Respondent filed its pre-hearing exchange which included its informal brief (Resp. Br.), a list of proposed witnesses, and eight (8) exhibits (Resp. Ex. 1 and Resp. Exs. A-G). Respondent's exhibits included the declaration of one witness, Bablir Singh, the business owner.

On November 1, 2017, I held a prehearing conference in this case. During the prehearing conference call, the parties agreed to waive their right to cross examine witnesses. The parties were allowed an opportunity to file a motion opposing any of the exhibits submitted as evidence. Neither party has filed such a motion. In the absence of any objections, CTP Exs. 1-30, Resp. Ex. 1, and Resp. Exs. A-G are admitted into the record. The parties were also allowed to submit final briefs. On December 1, 2017, CTP filed its final brief (CTP Final Br.). Respondent filed its final brief (Resp. Final Br.) on the same date. As indicated at the pre-hearing conference, an oral hearing is not necessary in this matter, and I will decide this case based on the written record.

Analysis

I. Violations

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal 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). FDA and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. §§ 1140.14(a)(1)¹.

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

In its Complaint, CTP alleges that Respondent committed two violations of the Act and its implementing regulations within a twelve month period. Complaint ¶ 1. In its Answer, Respondent has denied the allegations. Answer at 2.

CTP's case against Respondent rests on the testimony of Inspector Griffin and Ms. Sternberg, plus corroborating evidence. CTP Exs. 3, 4. Inspector Griffin is an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 4, at 1-2. Inspector Griffin's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Inspector Griffin testified that he went to Respondent's place of business with a minor to conduct compliance check inspections. CTP Ex. 4, at 2-4. The initial inspection took place on February 13, 2016, and a follow-up inspection took place on April 16, 2016. *Id.* Prior to each inspection, Inspector Griffin confirmed that the minor was carrying his photographic identification, and that he did not have tobacco products in his possession. *Id.* During both inspections, Inspector Griffin witnessed the minor enter the establishment, and purchase a package of cigarettes from an employee at the establishment. *Id.* at 3, 4.

Inspector Griffin stated that after each purchase, both he and the minor exited the establishment and returned to his vehicle, where the minor immediately gave him the pack of cigarettes. Both purchases were observed to be a package of Camel cigarettes. *Id.* Inspector Griffin testified that, on February 13, 2016 and April 16, 2016, he labeled the cigarettes as evidence, and took photographs of the packages. *Id.* Inspector Griffin then testified that shortly after the inspections, he recorded the inspections in the FDA's Tobacco Inspection Management System. *Id.*

Ms. Sternberg is a Senior Regulatory Counsel with the Center for Tobacco Products. CTP Ex. 3, at 1. Ms. Sternberg testified that in her official capacity she has knowledge of the processes used by the FDA regarding the establishment registration and product listing requirements. *Id.* at 1-2. She further testified that the Camel cigarettes purchased on February 13, 2016 and April 16, 2016 at Respondent's establishment were manufactured by RJ Reynolds Tobacco Company in the State of North Carolina. *Id.* at 2-3. Ms. Sternberg confirmed that the cigarettes were not manufactured in Florida. *Id.* at 3.

CTP argues the testimonies of Inspector Griffin and Ms. Sternberg plus the corroborating evidence consisting of photographs of the pack of cigarettes that were obtained from the minor on February 13, 2016 and April 16, 2016, are proof that Respondent unlawfully sold tobacco products to a minor in violation of the Act. *See* CTP Final Br. at 10-13.

Respondent does not dispute Ms. Sternberg's testimony, but attempts to attack the credibility of Inspector Griffin. Respondent's defense focuses on Inspector Griffin's narrative report from the April 16, 2016 inspection. Particularly, Respondent argues CTP has not met its burden of proof that the April 16, 2016 violation occurred because Inspector Griffin's narrative report lists "Mohammed" as the name of the employee that sold tobacco products to a minor. Resp. Final Br. at 2; Declaration of Bablir Singh ¶ 18; Resp. Ex. F. Respondent argues that it does not employ anyone with that name. *Id.* Therefore, Respondent contends Inspector Griffin's entire testimony regarding the April 16, 2016 is false, and this calls into question his testimony regarding the February 13, 2016 inspection as well. Resp. Final Br. at 3. Respondent argues "there is no reliable evidence upon which the Court should find that the CTP has established any violation whatsoever." *Id.* at 9.

I have considered Respondent's arguments, but find them unpersuasive. Respondent has continued to assert that the tobacco sales to minors never occurred, but it has not provided any evidence to that effect, other than the unsubstantiated claim that Inspector Griffin has provided false testimony. Inspector Griffin testified under oath that he observed Respondent sell tobacco products to a minor on February 13, 2016 and April 16, 2016. In his April 16, 2016 narrative report, Inspector Griffin provided the following description of the employee who sold tobacco products to the minor:

Name: Mohammed
 Name observed on: Tag
 Gender: Male
 Age: Senior
 Hair: Gray/White
 Characteristics: Beard, Glasses

CTP Ex. 19, at 2.

Respondent argues that the employee time records for the Pay Period April 15, 2016 through April 21, 2016 reflect that no person named Mohammed worked at the Respondent's store during that time period. Resp. Final Br. at 3; Resp. Ex. 1, at 2; Resp. Ex. F. CTP argues that the various employment and training records submitted by Respondent reflect that the employee working on April 16, 2016 at approximately 3:29 PM² is referred to inconsistently. CTP Final Br. at 12; *see also*, Resp. Ex. F at 4. On the "Store Employee Summary" for the pay period

² The identified employee is documented as clocking in at 2:56 PM and clocking out at 6:00 PM on April 16, 2016.

ending April 21, 2016, as well as his individual “Store Employee Timecard”, this individual’s name is shown as “Khan H. Abdul.” Resp. Ex. F at 1, 4. On his most recent “Come of Age Completion Course Certificate,” his name is printed as “MDABDUL KHAN”, but signed as “HAMID.” Resp. Ex. D at 6. In another form submitted by Respondent to show employees’ acknowledgment of age restricted sales policies, the employee is identified simply as “HAMID.” Resp. Ex. E.

CTP additionally points out that in additional employment records submitted by Respondent, this same employee is identified by the first name “MD ABDUL, middle initial “H,” and last name “KHAN.” *See* Respondent’s Response to Complainant’s Motion to Compel Discovery and Extend Deadlines, Ex. A at 21. This document indicates Mr. Khan is a 70-year old male sales associate. *Id.*

Mr. MD Abdul H. Khan, who was working at the date and time of the sale to a minor, fits the gender and age of the employee listed on Inspector Griffin’s April 16, 2016 narrative report. None of the other employees working at the time of the violation meet the gender or age description. Additionally, as CTP noted, “MD” is a commonly used abbreviation for the name “Mohammed” in the Indian subcontinent which could have led to the confusion, or at least demonstrates that Respondent’s employees use names at work other than the ones on their payment records. CTP Final Br. at 13; *citing, Chowdhury v. Ashcroft*, 241 F.3d 848, 854, n.1 (7th Cir. 2001). CTP makes a compelling argument that this individual may have used a name tag reading “HAMID” or some variation of these names such as “MD HAMID”, which could have easily been read as Mohammed.

Respondent’s entire defense rests on the slight confusion with the name listed in Inspector Griffin’s April 16, 2016 narrative report. Respondent, who is represented by counsel, chose to waive cross-examination of Inspector Griffin and focus on the name discrepancy, as opposed to questioning Inspector Griffin and attacking his credibility at a hearing. While Respondent makes the variation in the name tag the focal point of its argument, Respondent does not deny that the employee working at 3:29 PM on April 16, 2016 meets the physical description detailed in Inspector Griffin’s narrative report. Furthermore, Respondent has provided no evidence concerning the lettering on the name tag that was, in fact, worn by this individual on April 16, 2016. Respondent’s attention to the confusion with the name listed on the April 16, 2016 narrative report appears to be more of a distraction than a significant source of evidence, and it does not lead me to disregard Inspector Griffin’s testimony.

Inspector Griffin’s sworn testimony establishes to my satisfaction that the violations charged in this case in fact took place on the dates in question.

Therefore, I find that the facts as outlined above establish Respondent HK 32216, Inc. d/b/a 7-Eleven 32216A's liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven 32216A 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 a \$275 civil money penalty against Respondent for two violations of the Act and its implementing regulations within a twelve-month period. Complaint ¶ 14. In both its Answer and its Final Brief, Respondent denied any obligation to pay a civil money penalty, asserting that it did not violate the regulations.

I have found that Respondent committed two violations of the Act and its implementing regulations within a twelve 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).

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

I have found that Respondent committed two violations of selling tobacco products to minors. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

ii. Respondent's Ability to Pay And Effect on Ability to do Business

Respondent has stipulated it has the ability to pay the \$275 civil money penalty sought by CTP. Respondent's Response to Motion to Compel, Ex. B.

However, Respondent claims that "[a] finding of a violation itself will have an extremely negative effect on Respondent's ability to do business." Resp. Final Br. at 12. Respondent states, as a 7-Eleven franchisee, its franchise agreement contains an "obey all laws provision that subjects Respondent to termination of its right to operate the franchise if it is found to have violated the law." *Id.* Respondent argues "a finding [that Respondent] violated 21 C.F.R. 1140.14 may constitute a breach of the franchise agreement, which would jeopardize its contractual right to continue its business." *Id.*

This, however, is a contractual matter between Respondent and 7-Eleven and Respondent's obligations under this agreement are independent of this proceeding.

Furthermore, Respondent had an obligation to be mindful of that provision prior to allowing repeated violations to occur. Accordingly, such contractual obligations do not weigh upon my decision. Additionally, it is unclear whether Respondent could continue to operate as a business regardless of its status as a 7-Eleven franchise. Based on the available evidence, I cannot conclude that a \$275 civil monetary penalty would severely hinder Respondent's ability to continue lawful retail operations.

iii. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. However, Respondent has violated the Act on two separate occasions. Following the February 13, 2016 inspection, CTP issued a warning letter to Respondent informing it of Inspector Griffin's documented violation. Complaint ¶ 11. That letter warned that Respondent's failure to correct its violation might result in a civil money penalty or other regulatory action. *Id.* Despite that warning letter, however, Respondent was found to have committed the exact same violation during an inspection only two months later on April 16, 2016. *Id.* ¶ 8.

iv. Degree of Culpability

Based on my finding that Respondent committed the violations in the Complaint, I hold it fully culpable for two violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

Respondent has detailed some of the steps it takes to prevent violations of the Act. Resp. Final Br. at 10-11. Respondent mandates its employees to complete a training program regarding the restrictions for tobacco sales. *Id.* Respondent 7-Eleven 32216A participates in the 7-Eleven Bars Program, a program that tests its employees by sending investigators to the store to conduct age restricted product sales. *Id.* at 11. Respondent also utilizes a point of sale ("POS") system to complete transactions involving age restricted products such as tobacco products. *Id.* at 10-11. The system requires an employee to either (a) manually enter a compliant date of birth provided by the customer or (b) swipe an identification with a compliant date of birth provided by the customer. *Id.* at 10.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$275 to be appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

