

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-3837)

Complainant

v.

The Greenlight Organization, Inc.
d/b/a 7-Eleven 10319A,

Respondent.

Docket No. T-17-743

Decision No. TB2233

Date: November 29, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, The Greenlight Organization, Inc. d/b/a 7-Eleven 10319A, located at 1301 Estero Boulevard, Fort Myers Beach, Florida 33931, 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 7-Eleven 10319A violated the Act by impermissibly selling cigarettes to minors.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$275 civil money penalty on Respondent 7-Eleven 10319A, at 1301 Estero Boulevard, Fort Myers Beach, Florida 33931, 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, following an order granting an extension of

time for the Respondent to file an answer. On February 14, 2017, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. CTP filed its pre-hearing exchange on June 9, 2017. Respondent filed its pre-hearing exchange on June 30, 2017. On August 31, 2017, I held a pre-hearing conference in this case. On October 31, 2017, both parties filed final briefs.

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. In its pre-hearing exchange, CTP submitted two witness declarations, while Respondent 7-Eleven 10319A submitted one witness declaration. During the pre-hearing conference, both parties waived their right to cross-examine proposed witnesses. The parties also agreed to waive their right to an oral hearing and proceed to submission of the case on the stipulated record. Therefore, I will decide this case on the basis of the written record. Neither party objected to the proposed exhibits, so I enter into the record CTP's Exhibits 1-25 (CTP's Ex. 1-25), and Respondent's Corrected Exhibit 1 (R's Ex. 1), and Respondent's Exhibits A-F (R's Ex. A-F).

Analysis

I. Violations

In its Complaint, CTP alleges that Respondent 7-Eleven 10319A committed two violations of the Act and its implementing regulations within a twelve month period. CTP makes the following allegations:

- At approximately 9:30 PM on December 15, 2015, at Respondent's business establishment, 1301 Estero Boulevard, Fort Myers Beach, Florida 33931, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age;
- In a warning letter dated December 29, 2015, CTP informed Respondent of the inspector's December 15, 2015, documented violation, and that such action violates federal law. The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 3:10 PM on March 24, 2016, at Respondent's business establishment, 1301 Estero Boulevard, Fort Myers Beach, Florida 33931, an FDA-commissioned inspector documented Respondent's staff selling a

package of Newport Box cigarettes to a person younger than 18 years of age.

Complaint; Informal Brief of Complainant.

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. The Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993). Respondent argues that CTP has failed to prove by a preponderance of evidence that the violations occurred.

Respondent argues that there is a disproportionate rate of failure in undercover tobacco inspections in the state of Florida. R's Ex. 1. at 5. Respondent also argues that the procedures used by inspectors in Florida when conducting undercover inspections, including the alleged customary practice to not obtain a receipt, have led to a pattern of errors and discrepancies that are difficult to challenge. *Id*; Respondent's Informal Brief at 9. I find these arguments to be irrelevant to the present action. My sole jurisdiction rests on the alleged sales that occurred at Respondent's establishment on December 15, 2015, and March 24, 2016, and I may only consider the evidence presented in relation to those alleged sales. I do not have the authority to consider inspections at other establishments and on other dates, nor do I have the authority to consider patterns that arise from other inspections.

Respondent calls into question the credibility of Inspector Galloway as a witness, and the accuracy of his narrative reports and written declaration. Respondent provided two newspaper articles indicating Inspector Galloway resigned from the St. Petersburg police department during an internal investigation of improper conduct regarding a police chase. R's Ex. B and C. Respondent provided no additional evidence regarding Inspector Galloway's credibility, and waived its right to cross-examine Inspector Galloway. I find and conclude that the evidence presented is not sufficient to impugn Inspector Galloway's capacity to perform the inspections in question, nor does the evidence damage Inspector Galloway's credibility in providing accurate information in his narrative reports and written declaration.

Respondent argues that CTP identified the tobacco product sold on December 15, 2015, as "Newport Box cigarettes," while the photograph taken by Inspector Galloway shows a soft pack of Newport cigarettes. Respondent's Informal Brief at 2; Respondent's Final Brief at 9; R's Ex. 1 at 6-7. CTP Ex. 9 at 3; CTP Ex. 11

at 1. I note that Inspector Galloway's narrative reports for the sales on both dates indicate that the tobacco product sold to the minor was "cigarettes in a package" and that brand name in both sales was "Newport." CTP Ex. 11 at 1; CTP Ex. 18 at 1. I also note that Inspector Galloway's written declaration identifies the tobacco product sold on both dates as "Newport cigarettes." CTP Ex. 9 at 3-4. The only reference to "Newport Box cigarettes" appears to be in CTP's complaint. Complaint at 3. I find and conclude that CTP's identification of the tobacco products in the Complaint as "Newport Box cigarettes" does not contradict the underlying evidence that Respondent sold tobacco products to minors on the dates in question.

Respondent argues that it would have been impossible for Inspector Galloway to witness the sales from outside Respondent's establishment because the views are obstructed by advertisements, and the sunlight glare on the establishment window would impede the inspector's view of the sale on March 24, 2016. Respondent's Informal Brief at 2; Respondent's Final Brief at 9-10; R's Ex. 1 at 7. Respondent has provided no additional evidence to support its claim. Further, it is unclear by the photographs provided by CTP whether Inspector Galloway's view was obstructed. CTP Ex. 15; CTP Ex. 22. Based on a preponderance of the evidence, I find and conclude that Inspector Galloway witnessed the transactions in question on December 15, 2015, and March 24, 2016, as stated in Inspector Galloway's narrative reports and written declaration.

Based on the record as a whole, I conclude that CTP has established by a preponderance of the evidence that a minor entered Respondent's establishment and purchased a package of cigarettes from an employee on December 15, 2015, and March 24, 2016. Therefore, I find that CTP has met its burden to establish Respondent 7-Eleven 10319A'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),¹ no retailer may sell cigarettes to any person younger than 18 years of age.

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

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent 7-Eleven 10319A 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, \$275, against Respondent for two violations of the Act and its implementing regulations within a twelve month period. Complaint ¶ 1. 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

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 should be set accordingly.

ii. Respondent's Ability to Pay

Respondent does not dispute that it has the ability to pay a \$275 civil money penalty.

iii. Effect on Ability to do Business

Respondent argues that a violation of federal tobacco regulations would jeopardize its franchise agreement and could have a significant impact on its ability to do business. Respondent's Informal Brief at 8. While I acknowledge that a finding of liability could jeopardize Respondent's franchise agreement, mitigation of the \$275 penalty would not alter my finding of liability. I conclude that Respondent has not proven how mitigation of the penalty amount would extricate Respondent from a breach of its franchise agreement.

iv. History of Prior Violations

The current action is the first civil money penalty action that CTP has brought against Respondent.

