

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2015-H-4864)

Complainant

v.

Deli-Icious Catering, Inc.  
d/b/a Convenient Food Mart,

Respondent.

Docket No. T-16-1674

Decision No. TB757

Date: January 18, 2017

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Deli-Icious Catering, Inc. d/b/a Convenient Food Mart, located at 500 Station Street, Wilmerding, Pennsylvania 15148, 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. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling tobacco products to minors, on two separate occasions, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on two separate occasions.

### Procedural History

CTP began this matter by serving an administrative complaint seeking a \$500 civil money penalty on Respondent, at 500 Station Street, Wilmerding, Pennsylvania 15148, 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. In its answer, Respondent denied the allegations.

CTP filed its pre-hearing exchange on September 1, 2016. CTP's pre-hearing exchange included the declarations of four witnesses. Respondent filed its pre-hearing exchange on September 29, 2016.

This matter was transferred to me on September 2, 2016. On September 8, 2016, I held a pre-hearing conference in this case. Following the pre-hearing conference, I issued an Order that scheduled the hearing for November 3, 2016. That Order noted that during the pre-hearing conference, Respondent indicated that it wanted to cross examine two of CTP's witnesses, Inspector Brittany Huffman and Inspector Kristen Police. After receiving Respondent's pre-hearing exchange, CTP indicated that it did not want to cross examine any of Respondent's proposed witnesses but preserved its right to cross examine Respondent's representative, Mr. Tom Setz.

On September 15, 2016, Respondent filed a Motion to Dismiss with Prejudice. CTP filed a response on September 26, 2016. I issued an Order on September 27, 2016, denying Respondent's Motion.

On November 3, 2016, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross examine Inspectors Huffman and Police. CTP chose not to cross examine Mr. Setz. During the course of the hearing, CTP objected to the witnesses provided by Respondent on the grounds that their statements were not properly written and submitted under penalty of perjury pursuant to 21 C.F.R. § 17.37(b). Hearing Transcript at 8-9. I agreed with CTP that these statements were not properly sworn and they were struck from the record. *Id.* at 9.

On November 21, 2016, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' post-hearing brief submissions as December 22, 2016. Both parties filed post-hearing briefs.

On December 16, 2016, Mr. Setz emailed the staff attorney assigned to this case and noted that he was having difficulty getting a paper copy of the hearing transcript. In his email, Mr. Setz stated he might require an extension of time to file his brief. No formal motion for extension was made. On that same date,

counsel for CTP emailed Mr. Setz a copy of the transcript. As a result, a By Direction Letter was issued letting the parties know that no action would be taken on Mr. Setz' question about an extension. It should be noted that Mr. Setz was given electronic access to the file on December 5, 2016.

## 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 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), (b)(1).

In its Complaint, CTP alleges that Respondent committed three violations of the Act and its implementing regulations within a twenty-four month period. Respondent filed an answer, and informal brief, that denied selling tobacco products to a minor. Answer; Informal Brief of Respondent.

CTP's case against Respondent rests on the testimony of Ms. Huffman and Ms. Police plus corroborating evidence. CTP Exs. 42, 43. Ms. Huffman is an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 42 at 1-2. Ms. Huffman's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Ms. Huffman testified that she went to Respondent's place of business on June 18, 2015. CTP Ex. 42 at 2-3. Ms. Huffman noted in her affidavit that upon inspection she saw a sign above the door that stated "Deli-Icious Chicken / Pizza" and a sign above the parking lot that stated "Convenience Food Mart." *Id.* at 2. Ms. Huffman further testified that on June 18, 2015, she confirmed that the minor was carrying his photographic identification, and that he did not have tobacco products in his possession. Ms. Huffman testified that the minor entered the establishment and went directly to the sales counter. Ms. Huffman stated that she saw the minor purchase a package of cigarettes from an employee of Respondent, and that the

minor did not provide photographic identification to the employee, and that the employee did not provide the minor with a receipt after purchase. *Id.* Ms. Huffman stated that after the purchase, the minor and she both exited the store and returned to her vehicle, where the minor immediately gave her the pack of cigarettes. The cigarettes were observed to be a package of Newport cigarettes. CTP Ex. 42 at 3. Ms. Huffman testified that she then labeled the cigarettes as evidence, and took photographs of the package. *Id.* Ms. Huffman then testified that shortly after the inspection she recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.*

Ms. Police is also an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 43 at 1-2. Ms. Police's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Ms. Police testified that she went to Respondent's place of business on September 20, 2015. CTP Ex. 43 at 2-3. Ms. Police further testified that on September 20, 2015, she confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. Ms. Police testified that the minor entered the establishment and went directly to the sales counter. Ms. Police explained that she stood a few feet away where she could hear and visually observe the transaction. *Id.* at 2. Ms. Police stated that she saw the minor purchase a package of cigarettes from an employee of Respondent, and that the minor did not provide photographic identification to the employee, and that the employee did not provide the minor with a receipt after purchase. *Id.* at 3.

Ms. Police stated that after the purchase, the minor and she both exited the store and returned to her vehicle, where the minor immediately gave her the pack of cigarettes. The cigarettes were observed to be a package of Newport cigarettes. CTP Ex. 43 at 3. Ms. Police testified that she then labeled the cigarettes as evidence, and took photographs of the package. *Id.* Ms. Police further testified that shortly after the inspection she recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.*

Ms. Police testified at the hearing that she did not observe any signage above Respondent's entrance, but that there is a sign on the corner of the building that reads "Convenient Food Mart." Ms. Police also explained that she located Respondent's business establishment using GPS. Hearing Transcript at 21-23.

The testimonies of Ms. Huffman and Ms. Police plus the corroborating evidence consisting of photographs of the packs of cigarettes that were obtained from each minor on June 18, 2015 and September 20, 2015, are proof that Respondent

unlawfully sold tobacco products to a minor, and failed to check the minor's identification before making the sales.

Throughout the case Respondent has denied that the sale of tobacco products to minors occurred and that the name of the retail establishment was misrepresented.

In its post-hearing brief, Respondent again asserts that the tobacco sales did not occur and that the name of the retail establishment was misrepresented. Respondent also appears to suggest that all of CTP's evidence is hearsay. Further, as an attachment to its post-hearing brief, Respondent seeks reconsideration of my Order granting CTP's motion to strike the written statements of Respondent's witnesses.

CTP's post-hearing brief asserts that it has proven by a preponderance of evidence that Respondent sold tobacco products to minors and failed to verify the age of the person purchasing those same tobacco products.

Respondent has argued that its legal name is Deli-Icious Catering, Inc. and that any correspondence sent to Convenient Food Mart should be disregarded. Specifically, Respondent has asserted that it is entitled to a new Warning Letter because the first one was addressed to Convenient Food Mart. I find that although Respondent may not consider Convenient Food Mart to be its legal name, there are sufficient grounds to determine that Respondent received the Warning Letter sent to "Convenient Food Mart" and that the Inspectors were not incorrect when they included the name in their reports. There was ample testimony provided along with photographic evidence showing that Respondent's establishment has a sign on the building reflecting the name "Convenient Food Mart." As a result, it is clear that whether or not Respondent does business under the name "Convenient Food Mart", tobacco products were sold to minors at Respondent's establishment on June 18, 2015 and September 20, 2015. There is further evidence that an employee of Respondent received the Warning Letter and sent a response back to CTP. CTP Ex. 20. As a result, I find that an allegedly improperly addressed Warning Letter does not sever Respondent's liability for its employee's sale of tobacco products to a minor.

Also, I have considered Respondent's request that CTP's evidence be stricken as hearsay, which is hereby denied. Under 21 C.F.R. Part 17, the Administrative Law Judge determines the admissibility of evidence and has discretion to apply the Federal Rules of Evidence when deemed appropriate. However, the Federal Rules of Evidence are not controlling in an administrative hearing. Ms. Police and Ms. Huffman personally witnessed the tobacco sale and observed the minor enter Respondent's establishment without cigarettes and subsequently leave the store with cigarettes in hand. That testimony, plus the corroborating evidence, leads to

the inference that the minors could only have obtained cigarettes by purchasing them at Respondent's business establishment.

Lastly, Respondent requests that I reconsider my order striking its written witness statements for failure to comply with 21 C.F.R. § 17.37(b). The regulation states that direct testimony shall be admitted in the form of a written declaration submitted under penalty of perjury. At the time of the hearing, I struck the statements because they were not made under oath. Respondent has now resubmitted the statements with a declaration page purported to be signed by the witnesses. However, this alleged declaration is now well past the September 29, 2016 due date. Regardless, even if the statements are considered, I do not find that they are enough to overcome the testimony and corroborating evidence presented by CTP.

As a result, I find that the facts as outlined above establish Respondent Deli-Icious Catering, Inc. d/b/a Convenient Food Mart's liability under the Act.

## **II. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Deli-Icious Catering, Inc. d/b/a Convenient Food Mart 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, \$500, against Respondent for three violations of the Act and its implementing regulations within a twenty-four month period. Complaint ¶ 1-2. In its Post-Hearing Brief, CTP continued to assert that a \$500 civil money penalty is appropriate. Post-Hearing Brief of Complainant at 9-10.

In both its Answer and its Post-Hearing Brief, Respondent denied any obligation to pay a civil money penalty because it did not violate the regulations.

I have found that Respondent committed three violations of the Act and its implementing regulations within a twenty-four 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). Respondent has presented copies of successful no sales on other inspections done by the State of Pennsylvania. Respondent also provided an explanation of new policies that it has implemented to help prevent any future sales of tobacco products to minors.

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

I have found that Respondent committed two violations of selling tobacco products to minors, and two violations for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. 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 not presented any evidence that it does not have the ability to pay the \$500 Civil Money Penalty sought by CTP.

**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. As noted above, Respondent has twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and twice violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). However, when Respondent submitted its prehearing exchange documents, it included evidence of inspections done by the State of Pennsylvania where tobacco products were not sold to minors.

**iv. Degree of Culpability**

Based on my finding that Respondent committed the three most recent violations in the current complaint, I hold it fully culpable for all three violations of the Act and its implementing regulations.

**v. Additional Mitigating Factors**

Respondent has also provided evidence that it has implemented new policies and no longer allows judgment calls from its employees about when to card tobacco product purchasers. Respondent explains that its employees must now card everyone who is in their mid-thirties and under.

