

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-0568)

Complainant

v.

NB Fuel, LLC
d/b/a Shell / Food Mart,

Respondent.

Docket No. T-16-29

Decision No. TB1607

Date: July 6, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, NB Fuel, LLC d/b/a Shell / Food Mart, located at 2090 West Oakland Park Boulevard, Oakland Park, Florida 33311, 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 2090 West Oakland Park Boulevard, Oakland Park, Florida 33311, 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. On May 17, 2016, I issued an Acknowledgment and Pre-Hearing Order (APHO).

On July 26, 2016, CTP filed a Motion to Compel Discovery, indicating that Respondent did not respond to its request for production within the time limit. *See* 21 C.F.R. § 17.23(a). In a letter issued by my direction, Respondent was given until August 10, 2016, to object to CTP's motion. Respondent did not file an objection to CTP's motion. On August 16, 2016, I issued an Order granting CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines for 30 days. On September 22, 2016, CTP filed an Updated Status Report, indicating that CTP had received Respondent's documents in response to CTP's Request for Production of Documents.

On September 23, 2016, CTP filed a Motion to Quash Respondent's Request for Production of Documents because Respondent's discovery request was not timely filed. On September 26, 2016, Respondent filed a response to CTP's Motion to Quash on the untimely filing issue. In a September 27, 2016 letter issued by my direction, CTP was given until October 7, 2016 to address Respondent's arguments.

On September 27, 2016, Respondent filed a Motion to Dismiss. On that same date, in a second letter issued by my direction, CTP was given until October 13, 2016 to file a response to Respondent's Motion to Dismiss.

On October 7, 2016, CTP filed a Response to the first By Direction Letter, dated September 27, 2016, in which it addressed Respondent's arguments concerning the Motion to Quash. On October 12, 2016, I granted CTP's Motion to Quash Respondent's Request for Production of Documents, finding that no extraordinary circumstances had been presented to justify an extension of Respondent's deadline to request documents from CTP.

On October 13, 2016, CTP filed its Opposition to Respondent's Motion to Dismiss, and on October 13, 2016, Respondent filed an Appeal/Review of my Order granting CTP's Motion to Quash, arguing that the requested documents were needed to defend itself. I construed Respondent's appeal as a Motion to Reconsider. On that same date, October 13, 2016, Respondent also filed a response to CTP's October 13, 2016 Opposition to Respondent's Motion to Dismiss. On October 26, 2016, I denied Respondent's Motion to Reconsider, noting that Respondent would receive much of the documentation that had been requested when CTP filed its pre-hearing exchange. On November 3, 2016, I denied Respondent's Motion to Dismiss, which I construed as a Motion for Summary Decision, as there were genuine issues of material fact in dispute.

CTP filed its Pre-Hearing exchange on November 10, 2016. Subsequently, on December 1, 2016, Respondent filed its Pre-Hearing exchange. On January 9, 2017, I held a pre-hearing conference in this case. During the pre-hearing conference, Respondent stated that it wanted to cross examine the minors involved in the inspections of its establishment. I informed Respondent that it would not be allowed to cross examine the minors. Following the pre-hearing conference, I issued an Order scheduling the hearing for January 31, 2017, noting that Respondent wished to cross examine two of CTP's witnesses, Inspector Ellen Feiler and Inspector Samantha Elberg. The January 31, 2017 hearing was postponed because of the unavailability of one of CTP's witnesses. On February 24, 2017, the parties filed a Joint Motion to Reschedule Hearing seeking a hearing date of March 9, 2017. On February 27, 2017, I issued an Order Rescheduling Telephone Hearing, setting the hearing for March 9, 2017.

On March 9, 2017, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross examine Inspectors Feiler and Elberg. During the course of the hearing, Respondent renewed its desire to cross examine the minors. Hearing Transcript at 12-21. As stated during the pre-hearing conference, I again informed Respondent that it would not be allowed to cross examine the minors. *Id.*

On March 28, 2017, 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 April 28, 2017. On April 27, 2017, Respondent filed a motion for extension to file its post-hearing brief. In my absence, Judge Margaret G. Brakebusch granted a 29 day extension to both parties to file their post-hearing briefs. On April 28, 2017, CTP filed its post-hearing brief. On May 30, 2017, Respondent filed its post-hearing brief along with another Motion to Dismiss and an unsigned statement from Dave Gustavo. On June 27, 2017, CTP filed a Motion to Strike Mr. Gustavo's statement.

Pending Motions

On May 30, 2017, Respondent filed a Motion to Dismiss that was incorporated in its post-hearing brief. Respondent's main argument is that CTP has provided insufficient proof that the violations allegedly documented on March 14, 2015 and October 5, 2015 actually occurred. Specifically, Respondent maintains that no cash register receipts were provided for the alleged sales as required, and the Inspectors never actually entered the store. For reasons that are discussed below, Respondent's Motion to Dismiss is **Denied**.

On June 27, 2017, CTP filed a Motion to Strike the unsworn and unsigned statement of Dave Gustavo. In its Motion, CTP argued that the statement should be stricken because it was not submitted "prior to the hearing as required by

21 C.F.R. § 17.25(a), and [is not] submit[ted] under perjury as required under 21 C.F.R. § 17.37(b).” Under 21 C.F.R. § 17.25(a), witness statements must be submitted at least 30 days before the hearing. Unless the presiding officer finds that extraordinary circumstances justified the failure to make a timely exchange of witness lists, she must exclude from the party’s hearing evidence the testimony of any witness whose name does not appear on the witness list. 21 C.F.R. § 17.25(b)(2). Here, Respondent did not submit a witness list and stated during the pre-hearing conference that it would not be producing any witnesses. Respondent has not demonstrated any extraordinary circumstances that prevented it from submitting a witness list or producing Mr. Gustavo as a witness before the hearing. CTP’s Motion to Strike is **Granted**, and the statement of Mr. Gustavo is excluded from the hearing 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 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 an informal brief, denying that tobacco products were sold to a minor. Answer; Informal Brief of Respondent.

CTP’s case against Respondent rests on the testimony of Ms. Feiler and Ms. Elberg plus corroborating evidence. CTP Exs. 4, 5. Ms. Feiler 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. Ms. Feiler’s inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.* Ms. Feiler testified that she went to Respondent’s place of business on March 14, 2015. CTP Ex. 4 at 2-3. Ms. Feiler further testified that on March 14, 2015, she confirmed that the minor was carrying her photographic identification, and that

she did not have tobacco products in her possession. *Id.* Ms. Feiler testified that the minor entered the establishment while she remained directly outside of the front door with an unobstructed view of the sales counter and the minor. *Id.* at 3. Ms. Feiler 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. Feiler stated that after the purchase, the minor exited the store and returned to her vehicle with her, where the minor immediately gave her the pack of cigarettes. CTP Ex. 4 at 3. The cigarettes were observed to be a package of Newport cigarettes. *Id.* Ms. Feiler testified that she then labeled the cigarettes as evidence, and took photographs of the package. *Id.* Ms. Feiler then testified that shortly after the inspection she recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.*

Ms. Elberg is also an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 5 at 1-2. Ms. Elberg's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Ms. Elberg testified that she went to Respondent's place of business on October 3, 2015. CTP Ex. 5 at 2-3. Ms. Elberg further testified that on October 3, 2015, she confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. *Id.* Ms. Elberg testified that the minor entered the establishment while she remained outside with a view of the sales counter and the minor. *Id.* at 3. Ms. Elberg stated that she saw the minor engage in a transaction with an employee of Respondent. *Id.*

Ms. Elberg stated that after the purchase, the minor exited the store, and they returned to her vehicle, where the minor immediately gave her the pack of cigarettes. CTP Ex. 5 at 3. The cigarettes were observed to be a package of Newport cigarettes. *Id.* Ms. Elberg testified that she then labeled the cigarettes as evidence, and took photographs of the package. *Id.* Ms. Elberg further testified that shortly after the inspection she recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.*

The testimonies of Ms. Feiler and Ms. Elberg plus the corroborating evidence consisting of photographs of the packs of cigarettes that were obtained from each minor on March 14, 2015 and October 3, 2015, are proof that Respondent unlawfully sold tobacco products to minors, and failed to check the minors' identification before making the sales

Throughout the case Respondent has denied that the sale of tobacco products to minors occurred and has repeatedly asked that either the minors or CTP identify the cashiers who sold the cigarettes to the minors. Additionally, Respondent has argued that there is insufficient proof because there are no receipts for the purchases.

In its post-hearing brief, Respondent again asserts that the tobacco sales did not occur and that a receipt is required to prove the allegations. Post-Hearing Brief of Respondent at 1. Respondent also maintains the position that the minors or the inspectors should identify the cashiers that sold the cigarettes and that without these identifications it cannot terminate a cashier. *Id.* at 1-2. Finally, Respondent asserts that the complaint should be dismissed because CTP failed to submit the sworn testimony of the minor. *Id.* at 3.

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.

I have considered Respondent's arguments, but find them unpersuasive. Respondent has continued to assert that the tobacco sales to minors/failure to verify their age never occurred, but it has not provided any evidence to that effect. Mere assertions alone are not sufficient. There is no provision in the applicable regulations requiring proof of purchase in the form of a cash register receipt. The evidence of record sufficiently identifies the cashiers who made the sales to the minors, and the sworn testimony of the Inspectors establishes to my satisfaction that the violations charged in this case in fact took place on the dates in question.

The identity of the State-contracted undercover buy minors is protected, and their statements to the Inspectors who accompanied them are included in the Inspectors' sworn testimony. A decision on the facts of the case is made based on a careful consideration of the entire record, without the sworn testimony of the minors.

I find that the facts as outlined above establish Respondent NB Fuel, LLC d/b/a Shell / Food Mart's liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent NB Fuel, LLC d/b/a Shell / 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 2.

In both its Answer and its Post-Hearing Brief, Respondent denied any obligation to pay a civil money penalty because there is insufficient proof it violated 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).

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 pre-hearing exchange documents, it included evidence of audits done by mystery shoppers that were successful, and Respondent has not had any violations since 2015.

iv. Degree of Culpability

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

v. Additional Mitigating Factors

Respondent has presented copies of two mystery shopper reports showing successful audits of the establishment. Respondent also stated that changes have been made to employee training and a new scanner system is in use that requires the swiping of customer identification to sell tobacco products to help prevent any future sales of tobacco products to minors.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$125 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$125 against Respondent, NB Fuel, LLC d/b/a Shell / Food Mart, 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