

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-R-3379)

Complainant

v.

Kuma H. Mamie  
d/b/a 7-Eleven Store 22921A,

Respondent.

Docket No. T-17-288

Decision No. TB2335

Date: December 27, 2017

**INITIAL DECISION**

I hereby impose a No-Tobacco-Sale Order against Respondent, Kuma H. Mamie d/b/a 7-Eleven Store 22921A, for a period of 30 calendar days, for five repeated violations of federal tobacco regulations over a period of 36 months.

**I. Background**

The Center for Tobacco Products (“CTP”) seeks to impose a No-Tobacco-Sale Order (“NTSO”), for a period of 30 calendar days, against Respondent, Kuma H. Mamie d/b/a 7-Eleven Store 22921A (“Respondent”), located at 8101 Fenton Street, Silver Spring, Maryland 20910, for five repeated 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 thirty-six (36) month period. CTP’s Complaint alleges that Respondent’s staff impermissibly sold tobacco products to minors and failed to verify that tobacco product purchasers were of sufficient age, thereby violating the Federal Food, Drug, and

Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140.

The complaint likewise alleges that Respondent previously admitted to violations of regulations found at 21 C.F.R. pt. 1140. Specifically, CTP alleges that Respondent committed: (1) One original violation and three repeated violations of sale to a minor, in violation of 21 C.F.R. § 1140.14(a)(1)<sup>1</sup>, on December 13, 2012, November 19, 2013, October 2, 2014, and January 30, 2016; and (2) One original violation and two repeated violations of failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(a)(2)(i), on December 13, 2012, October 2, 2014, and January 30, 2016. *See* Complaint ¶¶ 1, 10, 13-15; *see also* Informal Brief of Complainant at 1. Therefore, CTP seeks the imposition of an NTSO against Respondent for a period of 30 consecutive calendar days.

## II. Procedural History

CTP began this matter by serving an administrative complaint, seeking an NTSO for a period of 30 calendar days, on Respondent at 8101 Fenton Street, Silver Spring, Maryland 20910, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On November 17, 2016, Respondent timely filed an Answer ("Answer"). On December 9, 2016, I issued an Acknowledgment and Pre-Hearing Order ("APHO") that set out the deadlines for the parties' submissions in this case, and issued informal briefs for the parties to complete and submit.<sup>2</sup>

On March 30, 2017, CTP filed its pre-hearing exchange. CTP's pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and

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

<sup>2</sup> I note the following discovery matters concerning Respondent's Answer and CTP's document requests. On November 17, 2016, Respondent submitted two compact discs with its Answer. On December 6, 2016, by my direction, the compact discs were returned to Respondent with instructions on the proper format and size required for submission. Respondent did not resubmit the compact discs. On February 17, 2017, CTP filed a Motion to Compel. In a February 22, 2017 letter, Respondent was granted until March 3, 2017, to respond to CTP's Motion to Compel. On March 3, 2017, Respondent filed a response to CTP's Motion and documents related to their request. In a March 13, 2017, letter, I instructed parties to file a Joint Status Report not later than March 20, 2017. On March 16, 2017, the parties filed a Joint Status Report and CTP withdrew its Motion to Compel Discovery.

twenty-eight (28) numbered exhibits. CTP's exhibits included the declarations of two witnesses. The Respondent did not file a pre-hearing exchange.

On May 23, 2017, I held a pre-hearing conference in this case. During the prehearing conference, I explained that the sole purpose of a hearing under the applicable regulations was to allow for the cross-examination and re-direct of any witnesses who had provided sworn testimony in pre-hearing exchanges, and only if the opposing party elected to cross-examine the witness. Respondent communicated his desire to cross-examine only one of CTP's witnesses, Inspector Josephine Laney.

On July 13, 2017, I held a hearing in this case. During the course of the hearing, I admitted CTP's exhibits. Respondent cross-examined Inspector Laney. *See* Hearing Transcript at 8-15. CTP then conducted a redirect examination of Inspector Laney. *See* Hearing Transcript at 21-22.

On August 3, 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 October 6, 2017. Respondent filed a post-hearing brief ("Resp. Post-hearing Brief"). As the briefing period is over, I now render my decision.

### **III. Issues**

- A. Whether Respondent 7-Eleven Store 22921A sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age, on January 30, 2016, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).
- B. Whether an NTSO for a period of 30 calendar days is reasonable.

### **IV. Applicable Regulations and Guidelines**

CTP determined to impose an NTSO 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 (C.F.R.). 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 Food and Drug Administration (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. § 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)(1), (2).

The Act provides for civil money penalties ("CMPs") and NTSOs. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed "repeated violations" of restrictions on the sale of tobacco products. The term "repeated violations" is defined to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet . . . ." *See*

FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3,5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>.

I find that under 21 U.S.C. § 333(f)(8), I have the authority to impose an NTSO.

## V. Analysis

### A. Alleged Violations, Parties' Contentions, and Findings of Fact

CTP alleges that Respondent committed five repeated violations of the Act and its implementing regulations over a 36-month period. *See* Complaint at ¶ 1. CTP states that it did not include any repeated violations that occurred outside of the 36-month period or any violations of other Act sections that are not at issue in this case. *Id.* at note 1.

In its Complaint, CTP alleged that at approximately 8:27 a.m. on January 30, 2016, at Respondent's business establishment, 8101 Fenton Street, Silver Spring, Maryland 20910, 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 ¶ 4; *see* Informal Brief of Complainant at 4. The inspector 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. *Id.*

In its Answer, Respondent denies the latest alleged violations. Answer at 1- 3. Although Respondent indicated its belief that the NTSO CTP requests is appropriate in its Answer, Mr. Mamie also states that the imposition of an NTSO will put his franchise in jeopardy. Resp. Post-hearing Brief at 3.

#### 1. Parties' Contentions and Evidence

CTP's case against Respondent relies on the testimony of Inspector Laney who accompanied by a confidential state-contracted minor ("Minor 023"), conducted an undercover buy portion of a follow-up compliance check inspection at 7-Eleven Store 22921A, on January 30, 2016. Informal Brief of Complainant at 4. As evidence,<sup>3</sup> CTP provided a sworn declaration from Inspector Laney. *See* Laney Declaration, CTP Ex. 27. Inspector Laney is an FDA-commissioned officer with the State of Maryland, Behavioral Health Administration. *Id.* ¶ 2. Her duties include conducting undercover inspections to determine whether retailers comply with the age and photographic identification requirements relating to the sale of tobacco. CTP Ex. 27 ¶¶ 1-2. CTP provided a copy of the Compliance Check Inspection Notice, CTP Ex. 21; Inspector Laney's Narrative Report of the undercover inspection, Narrative Report, CTP Ex.20; the TIMS Form, CTP Ex. 19; and a redacted copy of the Minor 023's identification ("ID"), CTP Ex. 8. Finally,

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<sup>3</sup> The evidence discussed in this paragraph is not exhaustive.

Respondent cross-examined Inspector Laney at the July 13, 2017 hearing. *See* Hearing Transcript at 8-15.

Respondent raises several arguments in defense to CTP's allegations. Mr. Mamie asserts that on January 30, 2016, he along with a female employee were working at the register at the time of the inspection and that he did not sell any tobacco products to a minor. Answer at 2. He also states that the register used in his establishment, "automatically inform [sic] employees to check for valid identification card. As 7-Eleven rules and regulation prescribes..." *Id.* Mr. Mamie further states that he viewed the video surveillance footage from January 30, 2016, and did not see any violations. *Id.* at 3.

During the hearing, Respondent's cross-examination of Inspector Laney centered on questions regarding CTP's evidence that the cigarettes allegedly purchased by Minor 023 were purchased from Respondent's store. *See* Hearing Transcript at 13-15. During the hearing Respondent attempted to introduce testimony based on his recollection of what occurred in the retail establishment on January 30, 2016. *See* Hearing Transcript at 8-15. I again explained to Respondent as I had done at the pre-hearing conference that he could not both represent the business in this proceeding and testify as a witness. Even if he had not been representing the store, Respondent would not have been allowed to testify because no testimony was submitted in the form of a written declaration under oath and filed with the Civil Remedies Division by the hearing exchange deadline, as required by the APHO. *See* Hearing Transcript at 19-20. Lastly, even if he had standing as a potential witness, he would not have been allowed to testify at the hearing unless CTP had opted to cross-examine him.

Finally, in its Post-hearing Brief, Respondent reiterates his position that he was working in the retail establishment on the date and time of the alleged violations. Resp. Post-hearing Brief at 3. Respondent also argues that his business should be exonerated from the allegations because (1) CTP's evidence does not include the name of the employee who allegedly made the sale; (2) there was no receipt provided to prove a tobacco sale occurred; and (3) the establishment did not have any complaints for selling tobacco products to minors between 2003 and 2012. *Id.* at 1-3.

Respondent has not submitted evidence sufficient to rebut CTP's allegations. First, Respondent's claim that he was working the register on the date and time of the alleged violations supports Inspector Laney's Narrative Report. *See*, CTP Ex.20. Although Inspector Laney did not provide the name of the employee working on the date and time of the alleged violations, the narrative report describes the employee as an adult male with black/dark brown hair and a mustache. *Id.* at ¶ 16. While Respondent successfully established that he was working the register at the time of the alleged violations, his memory of what occurred that day is not supported by any other evidence.

Although Respondent argues that the cash register used in its establishment requires employees to scan a government issued identification card when selling tobacco products, *See*, Answer at 2; Respondent did not submit photographs of the cash register or any other product specification evidence to support its claim. Respondent did submit

compact discs which it claims contained video surveillance footage of the date and time of the alleged violations; however Respondent did not submit the discs in the proper size and format required for this court to admit and consider the video footage as part of the record.<sup>4</sup>

Respondent also argues that the alleged violations did not occur because CTP did not provide a receipt of purchase. In the absence of any requirement that a receipt is required for proof of purchase, and the possibility of other explanations, including that a receipt may not have been provided by the sales clerk, this argument is not persuasive. Furthermore, it is contradicted and outweighed by the highly credible testimony of Inspector Laney. During the redirect examination conducted by CTP's counsel, Inspector Laney testified that she witnessed the alleged violations. I will not recite every detail of Inspector Laney's testimony but will highlight the testimony regarding the transaction.

This is the relevant excerpt of Inspector Laney's testimony during the redirect examination:

Q. Did you see what happened?

A. I absolutely did. And in my testimony, in my declaration here and if we turn our attention to item 12, line 12 where I said I observed that the tobacco product sold to the minor was cigarettes in a package. And after we exited the store, to answer Mr. Mamie's question, the minor, as it stated in my declaration, immediately gave me the cigarettes in the package. I was there. I witnessed it. The minor stood in front of me in line, purchased the cigarettes, we exited the store. Minor handed the cigarettes over to me and I followed and completed my procedure. Again, that's what happened.

Hearing Transcript at 21-22.

## 2. Findings of Fact

I find that Inspector Laney testified credibly and comprehensively about her observations during the January 30, 2016, inspection at which she observed Respondent selling tobacco products to Minor 023. *See* Hearing Transcript at 21 -22, 45; Laney Declaration, CTP Ex. 27; Narrative Report, CTP Ex. 20.

Based on Inspector's Laney's testimony, I find that the violations occurred as she reported. Respondent's attempt to testify as to his personal recollection of the events on the date and time of the alleged violations are not admitted as a declaration under oath and therefore not considered in my decision. The December 9, 2016, APHO contained provisions that set out instructions regarding a party's submission of written direct testimony by a date certain. *See* APHO ¶¶ 9-10. "A witness statement must be submitted in the form of a written declaration that is **signed by the witness under penalty of**

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<sup>4</sup> On December 6, 2016, by my direction, the compact discs were returned to Respondent with instructions on the proper format and size required for submission. Respondent did not resubmit the compact discs.

**perjury for false testimony.”** See APHO ¶ 9 (emphasis added); see also 21 C.F.R §§ 17.25(a), 17.37(b).

I find that CTP has provided an abundance of evidence to support its allegation that Respondent (1) sold tobacco products to a Minor 023 on January 30, 2016, and (2) failed to verify that tobacco product purchaser was of sufficient age, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).

### **B. No-Tobacco-Sale-Order Penalty**

CTP proposes to impose an NTSO for a period of thirty (30) calendar days against Respondent for seven violations (two original and five repeated violations) of law in the period commencing December 13, 2012, and running through January 30, 2016.

To support their request for an NTSO for a period of thirty (30) calendar days in this matter, CTP refers to policy guidelines that establish maximum NTSO durations. Informal Brief of Complainant at 10-11. For a first NTSO, CTP recommends that the maximum duration be 30 calendar days. See CTP, U.S. FDA., U.S. Dep’t of Health & Human Servs., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order (August 2015)<sup>5</sup>. While the CTP guidance notes are not regulations and thus, are not binding, as a matter of law, I consider them to be persuasive.

When determining the period to be covered by an NTSO, 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).

#### *1. Nature, Circumstances, Extent and Gravity of the Violations*

I have found that Respondent committed a total of five repeated violations of FDA tobacco regulations within a period a 36-month period. His business has a history of three (3) previous CMPs filed against it in July 2013, July 2014, and June 2015, involving a total of 5 violations prior to the current violations in January 2016, that resulted in the 30-day NTSO complaint. Respondent’s repeated inability to comply with federal tobacco regulations raises a serious concern for the wellbeing of minors. CTP is correct that an NTSO is “necessary and appropriate to protect the public health.” See Informal Brief of Complainant at 12. Thus, I find that an NTSO of 30 calendar days is a reasonable penalty.

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<sup>5</sup> Determination of the Period Covered by a No-Tobacco Sale Order and Compliance With an Order: Guidance for Tobacco Retailers is available at: <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

## 2. Respondent's Ability to Pay

This factor does not apply to the circumstances here because the penalty sought is exclusion (NTSO) and not a monetary penalty.

## 3. Effect on Ability to do Business

Respondent claims that the imposition of an NTSO will put his franchise in jeopardy. Resp. Post-hearing Brief at 3. According to Respondent, the imposition of an NTSO is considered a material breach of his franchise contract with 7-Eleven. *Id.* Respondent submitted no evidence in support this contention. Additionally, it is unclear whether Respondent could continue to operate as a business regardless of its status as a 7-Eleven franchise. Respondent also states that it is losing “150 customers on average per day” and “13 % of daily sales” due to intense competition from other 7-Eleven stores located in close proximity to its location. Resp. Post-hearing Brief at 4. Based on the available evidence, I cannot conclude that a 30-day NTSO would severely hinder Respondent's ability to continue other lawful retail operations during the NTSO period. Moreover, “the need to protect the [minors] outweighs the adverse effects that an NTSO may have on an individual retailer's business, especially in light of the fact that imposition of this remedy is reserved only for those retailers who demonstrate indifference to the requirements of law.” *Kat Party Store, Inc., d/b/a Mr. Grocer Liquor Store*, CRD No. T-16-1684, at 3-4 (2016).

## 4. History of Prior Violations

It is undisputed that Respondent is a repeated violator of FDA's tobacco regulations prohibiting the sale of tobacco products to minors. The current action is the first NTSO action against Respondent for violations of the Act and its implementing regulations. As noted previously, Respondent has been the subject of three prior CMP actions. In addition to the original violations on December 13, 2012, and the two current violations on January 30, 2016, 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)(1), and once 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(a)(2)(1). *See* Complaint ¶¶ 1, 13-15.

The earlier CMPs were filed with regularity in July 2013, July 2014, and June 2015.

The first was decided by default when Respondent failed to answer. The second case was settled. In the third, Respondent admitted liability and asked for a reduced penalty which was granted in a decision issued on December 8, 2015, in consideration of efforts made to deter tobacco sales to minors after the violations in October 2014. Yet in January 2016, less than 2 months after the decision was issued, additional violations were documented, and appear to have been committed by Respondent himself. Respondent has an extensive history dealing with CTP complaints, is amply familiar with the process, but is unrepentant.



Respondent's continued failure to abide by the laws and regulations governing the sale of tobacco products indicates that the imposition of an NTSO may be the only way to deter Respondent from continuing to engage in unlawful sales of tobacco products.

*5. Degree of Culpability*

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

*6. Additional Mitigating Factors*

I do not find any mitigating factors. Respondent has not provided any evidence that it has implemented new policies for its employees about when to verify the age of tobacco product purchasers. Respondent asserts that 7-Eleven's policy requires sales associates to complete and pass a training course on the sale of age restricted products prior to employment. Resp. Post-hearing Brief at 3. While 7-Eleven may indeed have training programs that attempt to eliminate the illegal sale of tobacco products to minors, these training programs have proven ineffective in Respondent's establishment. Because Respondent is a habitual and unremorseful violator of the FDA tobacco regulations, I find that a 30-day NTSO is necessary.

**VI. Conclusion**

For these reasons, I impose a No-Tobacco-Sale Order against Respondent Kuma H. Mamie d/b/a 7-Eleven Store 22921A, for a period of 30 consecutive calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

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/s/  
Catherine Ravinski  
Administrative Law Judge