

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2018-R-1510)

Complainant,

v.

Exxon Express Inc.  
d/b/a Exxon Food Mart / S and S Food Mart,

Respondent.

Docket No. T-18-1939

Decision No. TB3878

Date: May 29, 2019

**INITIAL DECISION**

I hereby impose a No-Tobacco-Sale Order (“NTSO”) against Respondent, Exxon Express Inc. d/b/a Exxon Food Mart / S and S Food Mart (“Respondent”), for a period of 30 consecutive calendar days, for five repeated violations of federal tobacco regulations over a period of 36 months.

**Background**

The Center for Tobacco Products (“CTP”) seeks to impose an NTSO, for a period of 30 calendar days, against Respondent, located at 255 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, for five repeated violations of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 36-month period. CTP’s Complaint alleges that Respondent’s staff impermissibly sold cigarettes to a minor, failed to verify that the purchasers were purchasers were of sufficient age, and opened packages of cigarettes intended for the sale of individual cigarettes, thereby violating 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 two repeated violations of sale of cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)(1)<sup>1</sup>, on July 9, 2015, August 4, 2016, and November 30, 2017; (2) one original violation and two repeated violations of failure to verify the age of a person purchasing cigarettes or smokeless tobacco 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 July 9, 2015, August 4, 2016, and November 30, 2017; and 3) one original violation and one repeated violation of offering open packages of cigarettes intended for the sale of individual cigarettes, in violation of 21 C.F.R. § 1140.14(a)(4), on October 9, 2015, and November 17, 2017. *See* Complaint ¶¶ 1, 6, 9, 10; *see also* Informal Brief of Complainant at 1-2. Therefore, CTP seeks the imposition of an NTSO against Respondent for a period of 30 consecutive calendar days.

### **Procedural History**

CTP began this matter by serving an administrative complaint ("Complaint"), seeking an NTSO for a period of 30 calendar days, on Respondent at 255 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, and by filing a copy of the Complaint with the Food and Drug Administration's ("FDA") Division of Dockets Management. DAB E-File Docket ("Dkt.") #1, 1b.

On May 17, 2018, Respondent, through counsel, timely filed an Answer ("Answer"). Dkt. #3a. On May 29, 2018, 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. Dkt. #4-4b.

On August 15, 2018, pursuant to 21 C.F.R. § 17.23(a), CTP filed a Motion to Compel Discovery indicating that CTP had not received a response to its request for production of documents. Dkt. #7. On August 15, 2018, CTP also filed a Motion to Extend Deadlines. Dkt. #8. An August 21, 2018 letter issued by my direction allowed Respondent until September 5, 2018 to file a response to CTP's motion to compel discovery. Dkt. #10. On August 21, 2018, I also issued an Order that extended the parties' pre-hearing exchange deadlines. Dkt. #11.

On September 10, 2018, I issued an Order that granted CTP's motion to compel discovery. Dkt. #12. I noted that Respondent had not filed a response to CTP's motion to compel discovery. In that Order, I directed Respondent to comply with CTP's request for production of documents by September 26, 2018. I warned that "[f]ailure to do so

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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>.

may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint . . . .”<sup>2</sup> The September 10, 2018 Order also extended the parties’ pre-hearing exchange deadlines.

On October 2, 2018, CTP filed a Motion to Impose Sanctions advising me that Respondent had not complied with my September 10, 2018 Order and asking me to strike the Respondent’s answer and issue a default judgment in this case. Dkt. #13. In an October 4, 2018 letter issued by my direction, Respondent was given until October 19, 2018 to file a response to CTP’s motion. Dkt. #14. The October 4, 2018 letter also extended the parties’ pre-hearing exchange deadlines. On October 19, 2018, Respondent, through counsel, filed 1) Respondent’s Response to CTP’s Motion for Sanctions; and 2) Respondent’s Discovery Responses. Dkt. #16-17.

On August 20, 2018, CTP filed its pre-hearing exchange. Dkt. #9-9r. CTP’s pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and 17 numbered exhibits. CTP’s exhibits included the declaration of one witness, Inspector Pamela Smith.<sup>3</sup> CTP Exhibit (Ex.) 5. On October 11, 2018, Respondent filed a document captioned “Respondent’s Pre-Hearing Exchange.” Dkt. #15. Respondent’s exchange submission included an Informal Brief, identification of proposed exhibits and one proposed witness, Ibrahim Nadish, and a brief summary of the witness’s anticipated testimony.

On October 23, 2018, a letter by my direction was issued to the parties acknowledging receipt of Respondent’s October 11 and 19, 2018 filings, and advising Respondent that it had until the previously established November 19, 2018 deadline to file a pre-hearing exchange that complies with the directives established in the May 29, 2018 APHO. Dkt. #18, at 2. The letter also informed that, in the absence of submitting a pre-hearing exchange in compliance with the APHO, Respondent would be precluded from “presenting any exhibits, witness testimony, and/or witness statements at the hearing.” *Id.* Because CTP filed its exchange documents on August 20, 2018 and in compliance with the APHO, the letter also afforded CTP the opportunity to file a supplemental pre-hearing exchange, if any. Respondent did not respond to the October 23, 2018 letter.

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<sup>2</sup> I note that the September 10, 2018 Order inadvertently referenced imposition of “a civil money penalty.” It should correctly reference imposition of “a no-sale-tobacco order.” *See* Dkt. #12, at 2.

<sup>3</sup> Subsequent to the inspections at issue, Inspector Smith’s last name was changed to Smith-Grant. *See* Hearing Transcript (“Tr.”) at 4, 6. For the purposes of this decision, the inspector will be referenced by the name used at the time of the inspection – Inspector Smith.

On January 4, 2019, I held a pre-hearing conference (“PHC”) 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. We also discussed the parties’ pre-hearing exchanges and witnesses. Respondent’s counsel advised of his intent to cross-examine CTP’s witness, Inspector Smith. *See* Dkt. #20. Respondent’s counsel also advised that he would not present any witnesses at the hearing to provide testimony on Respondent’s behalf.

On January 28, 2019, I held a hearing in this case. During the course of the hearing, I admitted the parties’ exhibits. Respondent cross-examined Inspector Smith. *See* Tr. at 14-34. CTP then elected not to conduct a re-direct examination of Inspector Smith. *Id.* at 34.

On February 21, 2019, 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 March 25, 2019. Dkt. #22. Also, the parties were given until March 25, 2019 to file any corrections to the transcript. On March 25, 2019, CTP filed a Notice of Waiver of Post-Hearing brief. Dkt. #23. To date, Respondent has not filed any post-hearing submission. As the briefing period is over, I now render my decision.

### **Issues**

- A. Whether Respondent Exxon Food Mart / S and S Food Mart sold cigarettes to a minor, failed to verify that the cigarette purchaser was of sufficient age, and opened packages of cigarettes intended for the sale of individual cigarettes, on November 17 and 30, 2017, in violation of 21 C.F.R. § 1140.14(a)(1), 21 C.F.R. § 1140.14(a)(2)(i), and 21 C.F.R. § 1140.14(a)(4).
- B. Whether an NTSO for a period of 30 consecutive calendar days is reasonable.

### **Applicable Regulations and Guidelines**

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 (*revised* December 2016) at 3, 5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308>.

[htm](#). The Act also provides that “[p]rior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing . . . .” 21 U.S.C. § 333(f)(8).

The Act establishes the factors that must be considered in deciding on the length of an NTSO, but it does not specify the NTSO duration:

In determining the . . . period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , 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); *see also Kat Party Store, Inc. d/b/a Mr. Grocer Liquor Store*, CRD No. T-16-1684, at 2 (2016).

CTP’s guidance document establishes a maximum NTSO duration of 30 days for a retailer’s first NTSO. *See Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers* (August 2015) at 4, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

I find that under 21 U.S.C. § 333(f)(8), I have the authority to impose an NTSO. While the CTP’s guidance documents are not binding, as a matter of law, I consider them to be persuasive.

## Analysis

### I. Violations

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

CTP determined to impose an NTSO against Respondent pursuant to the authority conferred by the 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 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, the failure to verify the photographic identification of an individual who is not over the age of 26, and offering open packages of cigarettes intended for the sale of individual cigarettes are violations of implementing regulations. 21 C.F.R. § 1140.14(a)(1), (2), (4).

## 1. Alleged Violations

CTP alleges that Respondent committed five repeated violations of the Act and its implementing regulations over a 36-month period. *See* Complaint ¶ 1. CTP states that it only included repeated violations that occurred within a specified 36-month period after the original violations. *Id.* at 1 n.1. In its Complaint, CTP alleged that at an unspecified time on November 17, 2017, at Respondent’s business establishment, 255 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, an FDA-commissioned inspector observed open packages of cigarettes intended for the sale of individual cigarettes. Complaint ¶ 6; Informal Brief of Complainant at 4. The Complaint also alleges that at approximately 3:54 PM on November 30, 2017, at Respondent’s business establishment, 255 West Woodrow Wilson Avenue, Jackson, Mississippi 39213, an FDA-commissioned inspector documented Respondent’s staff selling a package of Newport Box cigarettes to a person younger than 18 years of age and failing to verify that the cigarette purchaser was of sufficient age. Complaint ¶ 6; *see also* Informal Brief of Complainant at 5-10.

Respondent concedes the past violations that were at issue in the two prior CMP actions against Respondent. *See* Answer ¶¶ 8-10. Respondent denies the current violation, and denies that it allegedly “committed a total of five repeated violations within a 36-month period.” *Id.* ¶¶ 4, 6, 11.

As Respondent has acknowledged that there have been past violations, (*see* Answer at ¶¶ 8-10), I find that the only issues before me, concerning violations, are: (1) whether Respondent sold cigarettes to a minor and failed to verify the purchaser’s age, on November 30, 2017, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i); and (2) whether Respondent opened packages of cigarettes for individual sale on November 17, 2017, in violation of 21 C.F.R. § 1140.14(a)(4), as alleged in the Complaint.

## 2. Parties’ Contentions and Evidence

### a. CTP’s Position

CTP’s case against Respondent relies on the testimony of Inspector Pamela Smith. Inspector Smith conducted a compliance check inspection on November 17, 2017. Informal Brief of Complainant at 6. Subsequently, the inspector, accompanied by a state-contracted undercover minor (Minor A), conducted a follow-up compliance inspection on November 30, 2017. Informal Brief of Complainant at 7-10. As evidence<sup>4</sup>, CTP provided a sworn declaration from Inspector Smith. *See* CTP Ex. 5 (“Smith Declaration”). Inspector Smith is an FDA-commissioned officer with the State of Mississippi. *Id.* ¶ 3. Her duties include “perform[ing] undercover buy (‘UB’) and

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<sup>4</sup> The evidence discussed in this paragraph is not exhaustive.

advertising and labeling ('A&L') inspections required under FDA's Tobacco Retail Inspection Contract with the state of Mississippi." *Id.* ¶¶ 3-4.

Inspector Smith declared that she conducted an A&L compliance inspection check of Respondent's establishment on November 17, 2017. CTP Ex. 5 ¶ 5. Inspector Smith stated that she entered the establishment and advised the most responsible employee available that she was conducting an A&L inspection. *Id.* ¶ 6. The inspector stated that while in the establishment she "observed that the establishment offered unpacked or repacked individual Newport Box cigarettes and Seneca Menthol 100's cigarettes for sale." *Id.* ¶ 8. Inspector Smith stated that prior to leaving the establishment, she issued a Form FDA 482, Notice of Inspection, to the individual on site who identified himself as the owner of the establishment. *Id.* ¶ 9; *see also* CTP Ex. 7.

With regard to the November 30, 2017 inspection, Inspector Smith declared that, prior to initiating the follow-up UB compliance check inspection, she confirmed Minor A's possession of his/her photographic identification, and that he/she did not possess any tobacco products. CTP Ex. 5 ¶ 14. The inspector stated that she watched Minor A enter Respondent's establishment, and that she entered moments after the minor. *Id.* ¶ 15. Inspector Smith asserted that she obtained an unobstructed view of the sales counter and directly observed Minor A purchasing a package of cigarettes from Respondent's clerk. *Id.* Inspector Smith noted that Minor A did not present any identification to the sales clerk, and the sales clerk did not provide a receipt after the sale. *Id.* Inspector Smith declared that, after the transaction, she and Minor A returned to the vehicle where the minor immediately handed the inspector the package of cigarettes. *Id.* ¶ 16. The inspector observed that the package of cigarettes contained Newport Box cigarettes. *Id.* Inspector Smith processed the evidence according to procedure and created a narrative report shortly thereafter. *Id.* ¶¶ 16-17.

Beyond Inspector Smith's declaration, CTP also provided evidence corroborating her testimony, including: photographs of the package of cigarettes Respondent unlawfully sold to Minor A (CTP Exs. 13, 14); a copy of the Compliance Check Inspection Notice (CTP Ex. 15); Inspector Smith's Narrative Reports of the inspections (CTP Exs. 8, 11); the TIMS Forms (CTP Exs. 9, 12); and a redacted copy of the Minor A's identification establishing his/her age at the time of the sale (CTP Ex. 10).

#### b. Respondent's Position

Respondent filed an answer and an informal brief, 1) denying that cigarettes were sold to a minor; 2) denying that Respondent failed to verify the minor's age during the November 30, 2017 inspection; and 3) arguing that the allegation regarding the open packages of cigarettes intended for sale of individual cigarettes is "without merits and has no factual basis." Answer; Informal Brief of Respondent. Respondent asserts:

. . . That there is no credible or admissible evidence contained in the exhibits before the Court proving that the alleged minor herein was younger than 18 or that the ID allegedly in possession of the alleged minor was not a “fake ID,” was validly issued by any lawful state agency and/or was legally obtained by the alleged minor.

That the CTP is unable to carry its burden, under any applicable standard, that the Respondent sold tobacco products to a person younger than 18 on November 17 and 30 2017.

In addition, the Respondent would show that the allegation contained in paragraph 6(c) is without merit and has no factual basis. The CTP’s argument that “the most responsible person stated that the establishment sells single cigarettes” is hearsay and is not admissible under any federal rules . . . .

Informal Brief of Respondent at 2.

In support of its assertions, and included as part of its pre-hearing exchange, Respondent submitted the narrative reports created by Inspector Smith and photographs taken by Inspector Smith during the November 17 and 30, 2017 inspections – all of which were submitted by CTP as part of its pre-hearing exchange. *See* CTP Exs. 8, 11, 13, 14. As part of its pre-hearing exchange, Respondent identified Ibrahim Nadish, manager of the establishment, as a proposed witness. Respondent’s Pre-Hearing Exchange at 2-3. However, Respondent did not file the written direct testimony of the proposed witness.<sup>5</sup>

c. Hearing Testimony

During the January 28, 2019 hearing, Respondent’s counsel challenged: 1) the validity of a violation for open packages of cigarettes in the establishment; 2) the integrity of the undercover inspection by attacking the credibility of Minor A; specifically, verification of the minor’s ID and assertions that CTP cannot prove that Minor A was not carrying a “fake ID;” and 3) the sale of cigarettes to a minor absent a receipt to prove the sale. *See* Tr. at 17-19, 21-22, 25-29, 30-33; *see also* Respondent’s Pre-Hearing Exchange at 2.

I find that Respondent’s argument is speculative and misguided. Inspector Smith testified credibly and comprehensively about her observations during the November 17 and 30, 2017 inspections at which she observed: 1) packages of cigarettes opened behind the sales counter; 2) the sale of cigarettes to Minor A; and 3) Respondent’s failure to

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<sup>5</sup> As previously discussed, during the PHC conducted on January 4, 2019, Respondent’s counsel advised that he would not present any witnesses at the hearing.



verify that Minor A was of sufficient age to purchase cigarettes. *See* Tr. at 18-19, 32; CTP Ex. 5 (Smith Declaration) ¶¶ 8, 14-15; CTP Ex. 8 (November 17, 2017 Narrative Report) ¶ 7; CTP Ex. 11 (November 30, 2017 Narrative Report) ¶¶ 9, 10. I will not recite every detail of Inspector Smith's testimony, but will highlight the points relevant to Respondent's stated arguments.

- November 17, 2017 Violation

First and foremost, CTP's Complaint did not allege a violation for sale of cigarettes to a minor, or to anyone, during the November 17, 2017 inspection. The violation alleged was pursuant to the regulations at 21 C.F.R. 1140.14(a)(4). Complaint ¶ 6.c. The regulation provides:

No retailer may break or otherwise open any cigarettes or smokeless tobacco package to sell or distribute individual cigarettes . . . .

21 C.F.R. 1140.14(a)(4). Inspector Smith testified credibly and comprehensively about her observations during the November 17, 2017 inspection. *See* Tr. at 17-23; CTP Ex. 5 ¶ 8.

Inspector Smith testified that she conducted an A&L compliance inspection at Respondent's establishment on November 17, 2017, at approximately 10:36 AM. CTP Ex. 5 ¶ 5; CTP Ex. 8 ¶ 2; Tr. at 17. At the hearing, with regard to the November 17, 2017 inspection, counsel for Respondent focused cross-examination of Inspector Smith on the issue of whether there is a violation if individual cigarettes are not sold. *See* Tr. at 18-20. At the hearing, the inspector testified that she observed open packages of cigarettes next to the establishment's cash register. Tr. at 21-22. On cross-examination, Inspector Smith testified, in part:

Q: And from looking at the narrative report . . . it says that the most responsible person stated that the establishment sells single cigarettes, is that correct?

A: Yes, sir.

Q: And who was that person?

A: It was the person at the cash register. I don't know his name.

Q: And you spoke with this person?

A: Yes, sir.

Q: And they told you that establishment sells single cigarettes?

A: Yes, sir.

\* \* \* \* \*

Q: . . . just so I understand your testimony, what you observed that day was a package of cigarettes on the counter, but there was no one selling those cigarettes, or no one purchased those cigarettes in your presence?

A: That's right. I did not see him purchase . . . actually purchase the single cigarettes. I just saw them on the counter beside the cash register.

Tr. at 17-18, 22.

In her written direct testimony, Inspector Smith explained that upon entering Respondent's establishment on November 17, 2017, she informed the most responsible person in the establishment that she was conducting an A & L inspection. CTP Ex. 5 ¶ 6. Consistent with her testimony during cross-examination, she testified that the individual confirmed that the establishment sells individual cigarettes. *Id.* ¶ 8. While she did not recall the name of the individual during cross-examination, she testified in her direct written testimony that the individual identified himself as the owner. *Id.* ¶ 9.

CTP submitted a copy of FDA Form 482, a Notice of Inspection that was completed and issued to Respondent at the time of the November 17, 2017 inspection. CTP Ex. 7. Inspector Smith testified that the notice was issued to the individual who identified himself as the owner and the form identifies Ibrahim Nadish as the owner of the establishment. CTP Ex. 5 ¶ 9; CTP Ex. 7.

Respondent did not present Ibrahim Nadish or any other individual as a witness to rebut Inspector Smith's testimony.

- November 30, 2017 Violations

The Complaint alleged that Respondent committed the violations of "selling cigarettes . . . to a minor, in violation of 21 C.F.R. § 1140.14(a)(1) . . . [.]" and "failing to verify the age of a person purchasing cigarettes . . . by means of photographic identification . . . as required by 21 C.F.R. § 1140.14(a)(2)(i)." Complaint ¶¶ 6.a, 6.b. On this issue, Inspector Smith's testimony was credible and concise as to her observations during the November 30, 2017 inspection. *See* Tr. at 23-34; CTP Ex. 5 ¶¶ 14-17; CTP Ex. 11 ¶¶ 2-7, 9-16.

On cross-examination, Respondent's counsel did not question Inspector Smith regarding the sales clerk's verification of the minor's identification. Instead, the questions focused on the inspector's verification of Minor A's identification, specifically, the validity of the minor's identification. Tr. at 26-29. Respondent's counsel also questioned the absence of a receipt for the purchase of the cigarettes. *Id.* at 31-33.

Inspector Smith testified that before the inspection at Exxon Food Mart / S and S Food Mart, she confirmed that Minor A had photographic identification showing his/her actual date of birth. *See* CTP Ex. 11 ¶ 6 (Narrative Report); CTP Ex. 5 ¶ 14 (Smith Declaration); Tr. at 26. During the cross-examination, Inspector Smith testified that she confirmed Minor A's identification. Tr. at 26. Inspector Smith testified that she went into the establishment with Minor A. *Id.* at 29. The inspector also testified that she was close enough to the counter to be able to hear any conversation between Minor A and the sales clerk. *Id.* at 32. Inspector Smith testified that she observed Minor A purchase a package of cigarettes from Respondent's sales clerk. *Id.* at 32.

This is the relevant excerpt of Inspector Smith's testimony during the cross-examination:

Q: And it also indicates that you confirm[ed] that the minor had a[n] ID showing his or her actual date of birth; is that correct?

A: That's correct.

Q: What agency issued the identification to the minor child?

A: Mississippi Department of Highway Patrol.

Q: And was it a driver's license?

A: No, sir. It was a permit.

\* \* \* \* \*

A: A learner's permit. I'm sorry, it was an identification card. Some . . . students have driver's license, some have identification cards but they are all issued by the Mississippi Department of Public Safety Highway Patrol.

\* \* \* \* \*

Q: And is it your testimony that the state of Mississippi issued identification cards to minors?

A: Yes.

\* \* \* \* \*

A: In order for a minor to work this program, the minor has to get an identification card issued from the Mississippi Highway Patrol.

Q: And the identification card has his date of birth or her date of birth?

A: Yes.

Q: And what was the minor child's date of birth in this case?

A: At the time, . . . August the 23rd of 2000.

\* \* \* \* \*

Q: Did the minor child obtain a receipt for the purchase?

A: No.

Q: Why not?

A: A receipt was not issued . . . by the clerk.

Q: Do you know if the minor child requested a receipt?

A: No, I do not.

\* \* \* \* \*

Q: [W]hat evidence do you have for this Court that this minor child purchased cigarettes that day?

A: I was in the store with the child and I saw the child purchase the cigarettes.

\* \* \* \* \*

Q: . . . [D]id the child use all of the money that was given to him?

A: I don't recall how much loose change[was] given to me by the minor.

Q: . . . Just so I'm clear, there was no receipt of the purchase and there was no - - You don't know if there was any change given back from the purchase?

A: Not that - - it was obviously given back, but I don't know how much change was given back from the purchase.

Q: And how much money was given to the child to do the purchase?

A: I don't remember that.

Tr. at 26, 29, 31-34.

### *3. Findings of Fact*

I find Inspector Smith's testimony to be credible. I find that CTP has provided an abundance of evidence to support its allegation that Respondent: 1) offered individual cigarettes for sale on November 17, 2017, in violation of 21 C.F.R. § 1140.14(a)(4); 2) sold cigarettes to Minor A on November 30, 2017, in violation of 21 C.F.R. § 1140.14(a)(1); and 3) failed to verify that Minor A was of sufficient age, in violation of 21 C.F.R. § 1140.14(a)(2)(i). I find that Respondent has failed to provide evidence to rebut CTP's allegations. As part of its pre-hearing exchange, Respondent identified one proposed witness to provide testimony at the hearing. However, Respondent did not submit written direct testimony in accordance with my APHO directives. Respondent subsequently advised of its intent not to present any witness testimony at the hearing. Further, Respondent has failed to submit any evidence which rebuts the allegations alleged in CTP's Complaint.

The facts as outlined above, establish that Respondent Exxon Express Inc. d/b/a Exxon Food Mart / S and S Food Mart is liable 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. § 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), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age. Further, 21 C.F.R. § 1140.14(a)(4) prohibits offering open packages of cigarettes for the purpose of sale of individual cigarettes.

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

I now address the second issue before me -- whether an NTSO for a period of 30 calendar days is a reasonable penalty. The undisputed facts of this case show that Respondent is a repeated violator of FDA's tobacco regulations. Respondent has been the subject of two prior CMP actions. *See* FDA Docket Number FDA-2016-H-0161; FDA Docket Number FDA-2017-H-0654. Between July 9, 2015 and November 30, 2017, Respondent sold cigarettes or smokeless tobacco to minors on three occasions. On those occasions, Respondent failed to verify by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age. Further, on two occasions, Respondent also possessed open packages of cigarettes for the sale of individual cigarettes. Complaint ¶¶ 1 (Table), 6, 8-10. For the purposes of the instant NTSO action, CTP counted the repeated violations that occurred on August 4, 2016, November 17, 2017, and November 30, 2017.

As previously mentioned, Respondent has conceded that the past violations occurred. Because Respondent already conceded the violations underlying the two previous CMPs, and as part of the settlement processes that concluded the prior CMPs, expressly waived its right to contest them in subsequent actions, there is no basis for questioning whether the current allegations are repeat violations. Thus, Respondent committed a total of five repeated violations of FDA's tobacco regulations over a 36-month period. Two prior settlements of the CMP actions did not deter Respondent from continuing to unlawfully sell tobacco products to minors. CTP now believes that, for Respondent's five repeated violations in a 36-month period, an assessment of a 30-day NTSO is appropriate. Informal Brief of Complainant at 14.

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).

#### **A. 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 36-month period. The repeated inability of Respondent to comply with federal tobacco regulations and its “unwillingness and/or inability to comply with the tobacco regulations” is serious in nature. *See* Informal Brief of Complainant at 3. Thus, I find that an NTSO of 30 calendar days is a reasonable penalty.

#### **B. 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.

#### **C. Effect on Ability to do Business**

Respondent has not presented any evidence about the effect of a 30-day NTSO on its ability to conduct its business. I am not persuaded that the NTSO would severely hinder Respondent Exxon Food Mart / S and S Food Mart’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).

#### **D. 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 two prior CMP actions. In addition to the original violations on July 9, 2015, and the current violations on November 30, 2017, Respondent has, on one occasion, violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and on one occasion violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i). Further, in addition to the original violation on October 9, 2015, Respondent has additionally violated the prohibition against possessing open packages of

cigarettes for the purpose of the sale of individual cigarettes, 21 C.F.R. § 1140.14(a)(4), on November 17, 2017. *See* Complaint ¶¶ 1, 6, 8-10.

### **E. 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.

### **F. Additional Mitigating Factors**

I do not find any mitigating factors. Respondent has neither expressed a willingness to comply with the FDA tobacco regulations nor presented a plan for correcting its violations. Because Respondent is a habitual violator of the FDA tobacco regulations, I find that a 30-day NTSO is necessary.

### **G. Penalty**

Under 21 U.S.C. § 333(f)(8), an NTSO is permissible for five (5) repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first NTSO received by a retailer is 30 consecutive calendar days. *See* Pub. L. 111-31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf> (last updated December 15, 2016).

Based on the foregoing reasoning, I find a penalty of an NTSO for 30 days to be appropriate under 21 U.S.C. §§ 333(f)(8).

### **Conclusion**

For these reasons, I impose a No-Tobacco-Sale Order against Respondent Exxon Express, Inc. d/b/a Exxon Food Mart / S and S Food Mart, 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.

/s/

Margaret G. Brakebusch  
Administrative Law Judge