

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-R-2455)

Complainant,

v.

Monroe Mobil, Inc.  
d/b/a BP,

Respondent.

Docket No. T-17-3655

Decision No. TB2767

Date: May 31, 2018

**INITIAL DECISION**

I hereby impose a No-Tobacco-Sale Order (NTSO) against Respondent, Monroe Mobil, Inc. d/b/a BP (Respondent), for a period of 30 consecutive 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 an NTSO, for a period of 30 consecutive calendar days, against Respondent, located at 2731 Monroe Street, Dearborn, Michigan 48124. CTP alleges that Respondent committed 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 36-month period. CTP's Complaint alleges that Respondent's staff impermissibly sold cigarettes to minors, thereby violating the Act, 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 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 asserts that Respondent committed: (a) one original violation and two repeated violations of a sale to a minor, in violation of 21 C.F.R. § 1140.14(a)(1),<sup>1</sup> on July 4, 2014, November 8, 2014, and September 11, 2015; and (b) 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 4, 2014, November 8, 2014, and September 11, 2015. *See* Compl., DAB E-File Docket (Dkt.) No. 1 ¶¶ 1 & 9-10. CTP, therefore, seeks the imposition of an NTSO against Respondent for a period of 30 consecutive calendar days.

## II. Procedural History

On April 20, 2017, CTP initiated this matter by serving an Administrative Complaint, seeking an NTSO for a period of 30 consecutive calendar days, on Respondent at 2731 Monroe Street, Dearborn, Michigan 48124, and filing a copy of the Complaint with the Departmental Appeals Board. Compl., Dkt. No. 1; Proof of Service, Dkt. No. 1b.

On May 22, 2017, Respondent, through counsel, timely filed an Answer. Answer, Dkt. No. 3. On May 25, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) setting out the deadlines for the parties' submissions in this case. APHO, Dkt. No. 4. I also explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than June 30, 2017. *Id.* at 7. I further explained that "a party receiving such a request must provide the requested documents no later than 30 days after the request has been made." *Id.* *See also* 21 C.F.R. § 17.23(a). On June 20, 2017, CTP, with Respondent's authorization, filed a joint status report. Joint Status Report, Dkt. No. 5.

On August 8, 2017, pursuant to 21 C.F.R. § 17.32, CTP filed a Motion to Compel Discovery indicating that CTP, consistent with the APHO, served a Request for Production of Documents (RFP) on Respondent on June 30, 2017, but received no response. Mot. to Compel, Dkt. No. 6, at 1; *see also* Dkt. Nos. 6a-6c. Although the APHO allowed a party ten (10) days from receipt of a RFP to file a Motion for a Protective Order (APHO, Dkt. No. 4, at 7), no such motion was filed by Respondent. CTP, therefore, requested "that an order be entered to require Respondent to comply with the [RFP] in its entirety." Mot. to Compel, Dkt. No. 6, at 1-2.

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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>.

On August 14, 2017, CTP timely filed its pre-hearing exchange. CTP's pre-hearing exchange included an Informal Brief of Complainant (Dkt. No. 7), a list of proposed witnesses and exhibits (Dkt. No. 7a), and exhibits 1 through 21 (Dkt. Nos. 7b-7v, respectively), containing the declaration of one witness, Inspector Justin J. Bishop (Dkt. No. 7v).

An August 16, 2017 letter issued by my direction allowed Respondent until August 30, 2017 to file a response to CTP's Motion to Compel Discovery. Aug. 16, 2017 By Direction Letter, Dkt. No. 8; *see also* 21 C.F.R. § 17.32(c). On the same date, consistent with 21 C.F.R. § 17.19(b)(17), I, *sua sponte*, issued an Order extending the CTP's and Respondent's pre-hearing exchange deadlines to September 13, 2017 and October 5, 2017, respectively. Aug. 16, 2017 Order, Dkt. No. 8a.

On August 22 and 23, 2017, Respondent filed its pre-hearing exchange. Respondent's exchange included a plan of action letter (Dkt. No. 10) and two images (Dkt. Nos. 9-9a). On August 30, 2017, Respondent's counsel, Michael L. Kalis, submitted Respondent's response to RFP. Dkt. No. 12. On August 31, 2017, Respondent, through counsel, filed its witness list (Dkt. No. 13), but submitted no sworn statements of direct testimony from any of the proposed witnesses.

On October 31, 2017, I held a pre-hearing conference (PHC) in this case. I explained that the sole purpose of a hearing under the applicable regulations was to admit the parties' exhibits and to allow for the cross-examination and re-direct of any witnesses who had provided sworn testimony. Respondent's counsel communicated the intent to cross-examine CTP's witness, Inspector Bishop. *See* Nov. 9, 2017 Order, Dkt. No. 15, at 1. I also noted that Respondent failed to submit any exhibits or sworn testimony for any witness intended to provide testimony at the hearing, as instructed in the APHO. *See* APHO, Dkt. No. 4, at 4 & 6-7.

On November 9, 2017, I issued an Order scheduling the hearing for December 18, 2017. *See* Nov. 9, 2017 Order, Dkt. No. 15, at 2. In that order, I allowed Respondent until November 17, 2017 to submit any supplemental pre-hearing exchange materials, subject to showing good cause for failing to submit its exchange materials by the exchange deadline. *Id.* at 1-2. I also allowed CTP until November 27, 2017 to respond to any supplemental pre-hearing exchange submitted by Respondent. *Id.* at 2.

On November 17, 2017, Respondent, through counsel, filed a Petition to Permit Respondent to Introduce Two Affidavits at Trial, attaching affidavits of two witnesses, Abed Farhat and Hassan Jawad. Pet. to Permit Resp't to Introduce Two Affs. at Trial, Dkt. No. 16. Respondent's petition claimed that "Respondent's counsel was unaware of the Department's Rules and Regulations" and "believed that answering the Interrogatories satisfied the . . . requirement . . . ." *Id.* at 1. On November 21, 2017, I issued an Order allowing CTP until December 4, 2017 to file a response to Respondent's

petition. Nov. 21, 2017 Order, Dkt. No. 17. On December 4, 2017, CTP filed its Opposition to Respondent's Petition to Submit Untimely Written Direct Testimony, requesting to deny Respondent's petition on the grounds that Respondent failed to demonstrate good cause for its submission of written testimony of two (2) proposed witnesses over a month after the pre-hearing exchange deadline. Opp'n to Resp't's Pet., Dkt. No. 18, at 2 (citing *CTP v. Ralph Baskerville d/b/a 4744 Corner Store*, No. 2013-1, 2012 WL 7849559, at \*2 (DAB Nov. 19, 2012)). On December 21, 2017, after careful review of the parties' submissions, I issued an Order denying Respondent's Petition to Permit the Introduction of Two Affidavits at Hearing, excluding the written statements of the two proposed witnesses, Abed Farhat and Hassan Jawad, from the record, and rescheduling the hearing. Dec. 21, 2017 Order, Dkt. No. 20

On February 1, 2018, I held a hearing in this case. During the course of the hearing, I admitted CTP's exhibits 1 through 21 over Respondent's evidentiary objections as to admissibility of the minor's redacted driver's license (CTP Ex. 3, Dkt. No. 7d). See Feb. 1, 2018 Hearing Transcript (Hr'g Tr.) 7:22-9:15. Respondent's counsel, Mr. Kalis, cross-examined Inspector Bishop. See Hr'g Tr. 10:8-16:21. CTP's counsel, Samantha Hong, then conducted a re-direct examination of Inspector Bishop. See Hr'g Tr. at 17:3-20:8.

On March 8, 2018, I issued an Order informing the parties that the Civil Remedies Division had received the transcript of the hearing, which was subsequently uploaded into DAB E-File (Dkt. No. 22), and set the deadline for the parties' post-hearing brief submissions as April 9, 2018. Mar. 8, 2018 Order, Dkt. No. 23, at 1-2. Also, the parties were given until April 9, 2018 to file any corrections to the transcript. *Id.* at 2. On April 9, 2018, Respondent, through counsel, filed Respondent's Post-Judgment Brief. Resp't's Post-J. Br., Dkt. No. 24. CTP did not file a post-hearing brief. As the briefing period is over, I now render my decision.

### **III. Issues**

- A. Whether Respondent, Monroe Mobil, Inc. d/b/a BP, sold cigarettes to a minor, on December 1, 2016, in violation of 21 C.F.R. § 1140.14(a)(1).
- B. Whether an NTSO for a period of 30 consecutive calendar days is reasonable.

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

CTP determined to impose an NTSO against Respondent pursuant to the authority conferred by the Act, 21 U.S.C. § 301 *et seq.*, and implementing regulations, 21 C.F.R. pt. 1140. 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).

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.

The Act provides for civil money penalties (CMPs) and NTSOs. Under 21 U.S.C. § 333(f)(8), an NTSO may be imposed 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, at 3 & 5-6 (Dec. 2016), <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf>. 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 developed policy guidelines that establish maximum NTSO durations. For a first NTSO, CTP recommends a maximum duration of 30 calendar days. *See* FDA Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers, at 4 (Aug. 2015), <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 guidance notes are not regulations and thus, are not binding, as a matter of law, I consider them to be persuasive.

## V. Analysis

### A. Allegations, 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* Compl., Dkt. No. 1 ¶ 1. CTP identified Respondent's original violations and Respondent's repeated violations that

occurred within a specified 36-month period after the original violations. *Id.* ¶ 1 n. 1; *see also id.* ¶ 1 (table).

As noted previously, the Complaint alleges that Respondent has been the subject of two prior CMP actions. In addition to the original violations on July 4, 2014, Respondent has twice 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 twice 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). *See* Compl., Dkt. No. 1 ¶¶ 1 & 8-10. CTP further alleges that the most recent repeated violation occurred at approximately 4:07 p.m. on December 1, 2016, at Respondent's business establishment, 2731 Monroe Street, Dearborn, Michigan 48124, when an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. *Id.* ¶ 6.

Since Respondent admitted to the previous violations as part of its settlement processes that concluded two prior CMP actions and expressly waived its right to contest them in subsequent actions (*see id.* ¶¶ 9-10), the only issue before me is whether Respondent sold cigarettes to a minor, on December 1, 2016, in violation of 21 C.F.R. § 1140.14(a)(1), as alleged in the Complaint. *Id.* ¶ 6.

In its Answer, Respondent alleges "Respondent trains his cashier[s] to ask for identification before selling cigarettes" and "Respondent has video surveillance<sup>2</sup> of cashier checking I.D." Answer, Dkt. No. 3 ¶ 1. In its defense, Respondent explains that the "[c]ashier did ask for identification from customer," but the "[c]ashier must have misread the driver's license." *Id.* ¶¶ 1-2. Respondent states that an NTSO is "inappropriate" because its prior violations from November 8, 2014 and September 11, 2015 should have counted as two violations rather than four. *Id.* ¶ 3. Respondent also avers that "Respondent has been in business for 25 years, [and] these are his only violations." *Id.*

Respondent's Plan of Action Letter similarly alleges that Respondent's staff is "well trained for the job and understands the laws of selling tobacco products." Resp't's Plan of Action Letter, Dkt. No. 10. Respondent further asserts that the surveillance video (that was never introduced into evidence) shows that the cashier asked for identification, but that "[t]he cashier must have misread the driver's license of the customer" and "even though a mistake was made, it should not reflect upon the whole business . . . ." *Id.* Respondent highlights its certification for not selling tobacco products to minors during a 2017 compliance check by The Knoph Company, Inc., a county designated youth tobacco use representative. *Id.* Respondent states that the cashier who made the sale was

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<sup>2</sup> Notably, Respondent never offered any surveillance video as evidence.

terminated “because mistake such as this is not something to repeat.” *Id.* Respondent claims that “[h]aving a no-tobacco-sale order for 30 days will have a large impact on the business as most of [Respondent’s] sales come from tobacco products and not the gas itself.” *Id.* Respondent filed two images (Dkt. Nos. 9-9a) with its Plan of Action Letter allegedly showing Respondent updated its point of sales systems to verify the age of every tobacco transaction allowing Respondent to know that a customer is underage by stating “Purchase Not Allowed.” *Id.* Respondent also states that it “will continue to monitor more ways to secure tobacco transactions and have an even stricter training regime for [its] employees.” *Id.*

CTP’s case against Respondent relies on the sworn declaration of Inspector Bishop who conducted a “follow-up undercover compliance check inspection at Respondent’s establishment located at 2731 Monroe Street, Dearborn, MI 48124, on December 1, 2016.” Informal Br. of Complainant, Dkt. No. 7, at 5; *see also* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶¶ 8-9. According to Inspector Bishop’s testimony, he was “accompanied by a confidential state-contracted minor, identified as 616 (‘Minor 616’).” *Id.* Inspector Bishop is an FDA-commissioned officer with the State of Michigan Department of Health and Human Services, employed by Prevention Michigan, Inc., a third-party state contractor. Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 2. His duties include conducting “undercover buy (‘UB’) inspections required under FDA’s Tobacco Retail Inspection Contract with the state of Michigan.” *Id.* ¶ 2. In further support of its position, CTP provided Inspector Bishop’s Narrative Report of the undercover inspection. Narrative Report, CTP Ex. 17, Dkt. No. 7r. CTP also provided a redacted copy of the Minor 616’s identification (ID). *See* Minor 616 Mich. State Issued ID Redacted, CTP Ex. 3, Dkt. No. 7d.

During the February 1, 2018 hearing, counsel for Respondent raised an objection to the admission of the redacted copy of the Minor 616’ driver’s license (CTP Ex. 3, Dkt. No. 7d), arguing the driver’s license is a hearsay and there is no foundation offered (such as the Minor 616’s narrative report). *See* Hr’g Tr. 7:22-9:12. I overruled the objections but allowed Respondent to raise them in its post-hearing brief. *See* Hr’g Tr. 9:12-15. During the cross-examination, Respondent’s counsel asked a question that was outside the scope of Inspector Bishop’s declaration. Specifically, Respondent’s counsel asked about the Minor 616’s narrative report not being included as evidence in this case. *See* Hr’g Tr. 10:11-18. I sustained CTP’s objection to this question. *See id.* Similarly, CTP’s counsel asked a question about the Minor 616’s narrative report on re-direct, and I sustained Respondent’s objection to this question. *See* Hr’g Tr. 18:8-19:5.

In its post-hearing brief, Respondent’s counsel challenged the integrity of the undercover inspection by implicitly attacking the credibility of Minor 616. Respondent’s argument focuses on verification of the minor’s ID and assertions that the redacted driver’s license of Minor 616 was not properly admitted into evidence. *See* Resp’t’s Post-J. Br., Dkt. No. 24, at 3. Respondent argues that there is no testimony as to what driver’s license was

produced by Minor 616 when she purchased cigarettes from Respondent. *See* Resp't's Post-J. Br., Dkt. No. 24, at 1 & 3; *see also* Hr'g Tr. 10:21-13:1. Respondent further asserts that "[t]here was no testimony to support a chain of evidence for the redacted driver[']s license" and since Inspector Bishop did not redact the driver's license of Minor 616, Inspector Bishop does not know whether the redacted driver's license was the license actually presented to the cashier by Minor 616. *See* Resp't's Post-J. Br., Dkt. No. 24, at 2-3; *see also* Hr'g Tr. 13:7-14:21. Respondent also contends that Inspector Bishop "did not take the minor's driver's license" nor "make a copy of the driver's license," and "[t]here is no testimony that the driver's license of minor 616 was, in fact, the redacted driver[']s license offered into evidence." *See* Resp't's Post-J. Br., Dkt. No. 24, at 2 & 4; *see also* Hr'g Tr. 16:2-19. Accordingly, Respondent argues that CTP failed to establish that Respondent violated 21 C.F.R. § 1140.14(a)(1), because the redacted driver's license is "flawed" and CTP cannot prove that Respondent sold cigarettes to a minor. Resp't's Post-J. Br., Dkt. No. 24, at 4.

These are the relevant excerpts of Inspector Bishop's testimony on cross-examination:

Q Mr. Bishop, you say you observed this transaction at the BP Mobile. You were behind the minor during this transaction; is that correct?

A Yes, sir.

Q All right. And could you see if the minor produced any ID?

A Yes, sir. In this case, the minor produced an ID.

Q Okay. But you don't know what ID that was, do you?

A Yes, sir. That was her -- that was the decoy's personal ID.

Q Okay. And how do you know that? Did you see that yourself? I mean, you were behind her.

A Yes, sir. With the protocol that we use, we verify that they have the correct ID for the work they do with us at the beginning of the day, and we observe that the only thing that they have on them is their ID and what we call the "buy" money, "purchase" money.

Q Okay. But how do you know there wasn't a different ID? You could not see that ID that was being presented to the cashier, could you?

A That's true, sir. I couldn't see it right there at the cashier.

\* \* \* \* \*

A The ID that was given was the one that was presented to me at the beginning of the day.

- Q Well, I don't know. You can't tell me or tell the Court what ID was presented to the cashier because you did not personally see the transaction; is that correct?
- A I did see the transaction, but the exchange of the ID was so quick I can't -- yeah. I was under, you know, the impression that was her ID, the only thing that she was carrying on her.
- Q You were under the impression, but you can't -- you can't say that you saw what ID was presented to the cashier?
- A That's correct. That's why we have our protocol, yeah.

\* \* \* \* \*

- Q Okay. All right. So this ID that's been submitted in this case as evidence, you didn't redact it. It was done by somebody else. Is that correct?
- A Yes, sir.
- Q Okay. So how would we know that this redacted ID was the identification presented to the cashier?
- A The date of birth matches the decoy. We do know the date of birth, and that matches.

\* \* \* \* \*

- Q Okay. All right. So you can't tell us today that this redacted driver's license was the license used at that time?
- A No. The only thing I can reference is the date of birth, the decoy's date of birth, sir.

Hr'g Tr. 10:21-11:22; 12:10-13:1; 13:17-14:2; 14:17-14:21.

I find that Respondent's arguments are misguided and speculative. Indeed, under 21 C.F.R. pt. 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, and I am not bound by the Federal Rules of Evidence in these proceedings. 21 C.F.R. § 17.39(b). I am only required to exclude evidence that is not relevant or material to the issues before me. 21 C.F.R. § 17.39(c). I may, however, exclude relevant evidence if I determine that its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence. 21 C.F.R. § 17.39(d). I find that the probative value of the redacted driver's license of Minor 616 (CTP Ex. 3, Dkt. No. 7d) is not substantially outweighed by the danger of unfair prejudice or confusion of the issues. I

find that the redacted driver's license of Minor 616 (CTP Ex. 3, Dkt. No. 7d) is relevant and reliable.

Indeed, Inspector Bishop's testimony provides credible and comprehensive overview of his verification of the Minor 616's age and driver's license during the December 1, 2016 inspection. *See* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶¶ 9-10; *see also* Narrative Report, CTP Ex. 17, Dkt. No. 7r ¶¶ 5-6 & 9. I will not recite every detail of Inspector Bishop's testimony but will highlight the points relevant to Respondent's contentions.

Inspector Bishop testified that all minors have to be 16 or 17 years old to be eligible to participate in undercover buy inspections. Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 6. Inspector Bishop further testified that he confirmed before the inspection that Minor 616 was under the age of 18. Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 9. Inspector Bishop also testified that before the inspection at Monroe Mobil, Inc. d/b/a BP, he physically verified that Minor 616 had photographic identification showing her actual date of birth and that Minor 616 had no tobacco products in her possession. *See* Hr'g Tr. 17:5-18:7; *see also* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 9; Narrative Report, CTP Ex. 17, Dkt. No. 7r ¶¶ 5-6. Inspector Bishop further testified that a true and accurate copy of Minor 616's ID was found at CTP exhibit 3 (Dkt. No. 7d) and he had no reason to believe otherwise. *See* Hr'g Tr. 19:8-16. Still further Inspector Bishop testified that neither his nor Minor 616's compensation depend in any way on whether or not they uncovered a violation. *See* Hr'g Tr. 19:17-20:6. Consistently, during the cross-examination, Inspector Bishop testified that under the protocol, he verifies that minors have the correct ID and observes that the only thing the minors have on them is their ID and "purchase" money. Hr'g Tr. 11:13-17. Inspector Bishop further testified on cross-examination that the date of birth on the redacted driver's license (CTP Ex. 3, Dkt. No. 7d) matches the date of birth of Minor 616. *See* Hr'g Tr. 13:21-142 & 14:17-21.

These are the relevant excerpts of Inspector Bishop's testimony on re-direct examination:

- Q Mr. Bishop, can you please take a look at your declaration, paragraph 9.
- A Yes.
- Q It states that, "Before the inspection I confirmed that minor 616 was under the age of 18 and possessed her true and accurate photographic identification showing her birth date as October 17, 2000." Do you see that?
- A Yes, ma'am.
- Q I believe when you were talking to Mr. Kalis you mentioned a protocol. Can you please clarify what you do to confirm that the minor has the accurate identification in possession before the inspection?

A Yes, ma'am. So at the beginning of the day, when we pick up our decoys, the decoys have to provide their ID to us, physical. They have to take it out, and we observe the ID through physical from holding the ID, and we make sure that everything is correct for that minor.  
And then after we physically verify the ID that they have, then they're asked to carry that in their pocket with buy money that we give them, and any other belongings such as purses or wallets, or something, is stored in the car. So throughout the day I'm ensuring that the decoy is not carrying anything in their pocket than the ID and the buy money.

\* \* \* \* \*

Q Back to paragraph 9 of your declaration, Mr. Bishop, the following sentence states that, "A true and accurate redacted copy of Minor 616's identification is found at CTP Exhibit 3." Do you see that?

A Yes, ma'am.

Q And if you take a look at CTP Exhibit 3, do you have any reason to believe that that statement is inaccurate?

A No, ma'am.

Hr'g Tr. 17:5-18:7; 19:8-16.

I find Inspector Bishop's testimony credible and the method Inspector Bishop used to verify the Minor 616's age and driver's license sufficient. Inspector Bishop examined the license, compared the photo on the license with Minor 616, confirmed Minor 616 was under 18 before the inspection, and verified Minor 616 had no tobacco product in her possession prior to entering the store.

Still further, CTP's Complaint did not allege a violation for failure to verify, by means of photographic identification, the age of a person purchasing cigarettes or smokeless tobacco (21 C.F.R. § 1140.14(a)(2)(i)) for the inspection conducted on December 1, 2016. The Complaint alleged only that, on December 1, 2016, "Respondent committed a violation of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)/1140.14(a)(1) . . ." Compl., Dkt. No. 1 ¶ 6. Inspector Bishop testified that he personally witnessed the purchase of a package of cigarettes by Minor 616 from an employee at the Respondent's establishment. *See* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 10; *see also* Narrative Report, CTP Ex. 17, Dkt. No. 7r ¶ 9. Inspector Bishop testified that he personally observed the transaction as he entered the Respondent's establishment immediately after Minor 616 and had an unobstructed view of the sales counter and Minor 616. *See* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 10. Inspector Bishop testified

that he personally witnessed that the clerk checked Minor 616's ID, but completed the sale. *See id.* *See also* Hr'g Tr. 10:21-11:6. Inspector Bishop further testified that he exited the store immediately after Minor 616 exited the store. *See* Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 11. Inspector Bishop testified that upon their entry of the vehicle, Minor 616 immediately handed over the package of Newport Box 100s cigarettes purchased at BP to Inspector Bishop. *Id.* Inspector Bishop's testimony supports Minor 616 was under age of 18 as Inspector Bishop confirmed Minor 616's age before the inspection. Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶ 9. Indeed, Respondent does not dispute that Minor 616 was under 18 at the time of the sale at issue. Similarly, Respondent does not dispute that the sale to Minor 616 on December 1, 2016 occurred.

I find that CTP met its burden and provided an abundance of evidence to support its allegation that Respondent sold cigarettes to Minor 616 on December 1, 2016, in violation of 21 C.F.R. § 1140.14(a)(1). I, therefore, find that Respondent sold cigarettes to Minor 616 on December 1, 2016.

In addition, the facts show that Respondent is a repeat violator who settled two prior CMPs. *See* Compl., Dkt. No. 1 ¶¶ 9-10. At the time of the December 1, 2016 violation, therefore, Respondent was aware of the FDA's enforcement program regarding tobacco sales to minors. Moreover, each complaint provides information regarding the relevant statutes and increasing penalties for additional violations, and a link to the guidance regarding penalties. *See, e.g.,* Compl., Dkt. No. 1 ¶¶ 2-3.

The facts as outlined above, establish that Respondent, Monroe Mobil, Inc. d/b/a BP, 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.

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

The second issue before me is whether an NTSO for a period of 30 consecutive calendar days is a reasonable penalty. The undisputed facts of this case show that Respondent is a repeat violator of FDA's tobacco regulations. Respondent has been the subject of two prior CMP actions. *See* FDA Dkt. No. FDA-2015-H-1270; CRD Dkt. No. C-15-2102, FDA Dkt. No. FDA-2015-H-4748, CRD Dkt. No. T-16-1673. Between July 4, 2014 and December 1, 2016, Respondent sold cigarettes or smokeless tobacco to minors on four occasions. *See* Compl., Dkt. No. 1 ¶¶ 1, 6 & 9-10. On three of 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. *Id.* ¶¶ 1 & 9-10.

CTP imposed two CMPs on Respondent but the CMPs did not deter Respondent from unlawfully selling tobacco products to minors. CTP requests that, for Respondent's five repeated violations in a 36-month period, an assessment of a 30-day NTSO is appropriate. Informal Br. of Complainant, Dkt. No. 7, at 10. Respondent argues that an NTSO is inappropriate because "[t]wo prior violations, 11/8/14 and 9/11/15 should be two violations not four." *See* Answer, Dkt. No. 3 ¶ 3. This argument is foreclosed by the *Orton* decision, which expressly upheld counting each instance of noncompliance with a tobacco regulation as an independent violation. *See Orton Motor Inc. v. U.S. Dep't of Health & Human Servs.*, 884 F.3d 1205, 1212-14 (D.C. Cir. 2018) (finding FDA's position that its enforcement authority permits to impose penalties for each violation of the tobacco sale restrictions arising during a single inspection or transaction a persuasive interpretation of the statute). Still further, 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, so there is no basis for questioning whether the current allegation is a repeat violation. *See* Compl., Dkt. No. 1 ¶¶ 9-10. Thus, Respondent committed a total of five repeated violations of FDA's tobacco regulations over a 36-month period from November 8, 2014 through December 1, 2016. *See id.* ¶ 1.

Although Respondent does not dispute its employee sold cigarettes to a minor on December 1, 2016, Respondent argues for mitigation of the NTSO because: (1) Respondent received a certification for not selling tobacco products to minors during a 2017 tobacco compliance check by its county designated youth tobacco use representative, (2) Respondent's owner allegedly ensures its staff is well-trained and understands the laws of selling tobacco products, (3) the cashier asked for identification from the customer as shown in the surveillance video (never offered as evidence), but allegedly misread the driver's license of the customer, (4) Respondent terminated the cashier conducting the sale, (5) Respondent updated a point of sales system to verify the age of every tobacco purchaser, and (6) Respondent "will continue to monitor more ways to secure tobacco transactions and have an even stricter training regime for [its] employees." *See* Resp't's Plan of Action Letter, Dkt. No. 10; *see also* Answer, Dkt. No. 3 ¶¶ 1-2. Respondent also claims that a 30-day NTSO would "have a large impact on the business as most of [its] sales come from tobacco products and not the gas itself." Dkt. No. 10.

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 36-month period. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature. Accordingly, I find that an NTSO of 30 consecutive calendar days is a reasonable penalty.

### 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 has not presented any evidence about the effect of a 30-day NTSO on its ability to conduct its business. A mere claim that a 30-day NTSO would “have a large impact on the business as most of [Respondent’s] sales come from tobacco products and not the gas itself” (Dkt. No. 10), without more, is not persuasive. Respondent presented no evidence that the 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*

Although the current action is the first NTSO action against Respondent, Respondent has a significant history of prior repeated violations of the Act and its implementing regulations prohibiting the sale of tobacco products to minors. Indeed, CTP imposed two CMPs on Respondent, but the CMPs did not deter Respondent from continuing to violate the tobacco regulations by unlawfully selling tobacco products to minors.

### 5. *Degree of Culpability*

Based on my finding that Respondent committed the most recent violation 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*

In its Plan of Action Letter (Dkt. No. 10), Respondent indicates that there is employee training and an updated point of sales system that verifies the age before tobacco product

sales, and notes Respondent's involvement in a local county program. While I commend Respondent's efforts, I do not find any mitigating factors. While Respondent may indeed have training programs and a point of sales system that attempt to eliminate the illegal sale of cigarettes or smokeless tobacco to minors, I am not persuaded that Respondent's efforts have been effective for Respondent's establishment. Additionally, this is the fifth violation within a short period of time for this store. Because Respondent is a habitual 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 Monroe Mobil, Inc. d/b/a BP, 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/

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Wallace Hubbard  
Administrative Law Judge