

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-R-2796)

Complainant

v.

Atty's Parti Expo, Inc.  
d/b/a Parti Expo,

Respondent.

Docket No. T-16-1990

Decision No. TB2263

Date: November 30, 2017

**INITIAL DECISION**

I hereby impose a No-Tobacco-Sale Order against Respondent, Atty's Parti Expo, Inc. d/b/a Parti Expo, 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, Atty's Parti Expo, Inc. d/b/a Parti Expo, located at 15201 West 7 Mile Road, Detroit, Michigan 48235, 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 Parti Expo 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 March 1, 2014, July 31, 2014, April 18, 2015, and November 13, 2015; 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 March 1, 2014, July 31, 2014, and November 13, 2015. *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 15201 West 7 Mile Road, Detroit, Michigan 48235, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On October 19, 2016, Respondent, through counsel, timely filed an Answer to Complaint and Request for Hearing ("Answer"). On November 15, 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 April 7, 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 twenty-five (25) numbered exhibits. CTP's exhibits included the declarations of two witnesses. On May 1, 2017, Respondent filed its pre-hearing exchange. Respondent's pre-hearing exchange included an informal Brief, a list of proposed witnesses 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 CTP's document requests. On January 9, 2017, CTP filed a Motion for a Protective Order. In a January 10, 2017 letter, Respondent was granted until January 23, 2017, to respond to CTP's Motion for a Protective Order. On January 23, 2017, Respondent filed a response to CTP's Motion for a Protective Order. On February 13, 2017, CTP filed a reply in support of its Motion for a Protective Order. On February 23, 2017, I issued a protective order that set out the provisions for the parties' document production and disclosure in this case.

exhibits, and seven (7) exhibits marked A-G. Respondent's exhibits included a written statement of one witness, Mr. Johnny Atty.

On May 17, 2017, CTP filed a Motion to Exclude Evidence not Exchanged in Accordance with 21 C.F.R. §§ 17.25 and 17.37(b) ("Motion to Exclude Evidence"). In that motion, CTP asked that I exclude the testimony of two of Respondent's proposed witnesses because Respondent failed to include their sworn statements with its exchange. On May 24, 2017, Respondent filed an Opposition to CTP's Motion to Exclude Evidence.

On June 9, 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's counsel communicated his desire to cross-examine only one of CTP's witnesses, Inspector Timothy Shafto. He declined to cross-examine Ms. Laurie Sternberg, who indicated that the tobacco products (allegedly) sold in Michigan were grown elsewhere, and had crossed State lines, therefore subject to interstate commerce laws. Further, Respondent's Counsel communicated his intent to stipulate to Ms. Sternberg's statements. CTP's Counsel communicated her desire to cross-examine Respondent's only witness who provided written testimony as part of the exchange, Mr. Johnny Atty.

During the prehearing conference, I also informed the parties of my ruling on the arguments presented in CTP's May 17, 2017 Motion to Exclude Evidence, and Respondent's May 24, 2017 Opposition. I noted that Respondent's exchange only included "written testimony under oath from one witness, Johnny Atty, the third co-owner of the business, and none from the two other co-owners who were named on Respondent's witness list."<sup>3</sup> Accordingly, I ruled that Mr. Johnny Atty was the only witness for Respondent eligible to appear at the hearing. On June 14, 2017, I memorialized my ruling in an order scheduling a hearing and granting CTP's Motion to Exclude Evidence.

On August 17, 2017, I held a hearing in this case. During the course of the hearing, I admitted the parties' exhibits. Respondent's Counsel cross-examined Inspector Shafto. *See* Hearing Transcript at 10-40. CTP then conducted a redirect examination of Inspector Shafto. *See* Hearing Transcript at 40-45. Although I administered the oath to Inspector Shafto and Mr. Atty, CTP's Counsel decided not to cross-examine Mr. Atty.

On September 8, 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

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<sup>3</sup> I note that Mr. Johnny Atty's statement is not, in fact, a "sworn statement," but rather, an offer to provide one. *See* Mr. Johnny Atty's statement, ("Exhibit C") at 2 ("I am willing to testify to this under oath and under penalty of perjury if necessary.")

October 5, 2017. Respondent filed a post-hearing brief (“Respondent’s Post-hearing Brief”). As the briefing period is over, I now render my decision.

### III. Issues

- A. Whether Respondent Parti Expo sold tobacco products to a minor and failed to verify that tobacco product purchaser was of sufficient age, on November 13, 2015, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).
- B. Whether the 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>. 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* 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 guidance notes are not regulations and thus, are not binding, as a matter of law, I consider them to be persuasive.

## 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 2:07 p.m. on November 13, 2015, at Respondent's business establishment, 15201 West 7 Mile Road, Detroit, Michigan 48235, 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. Complaint ¶ 10; *see* Informal Brief of Complainant at 3. 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 denied the "allegations stated in the Complaint, including the latest alleged violation." Answer ¶¶ 1, 10, 15. Respondent also denied having violated the enumerated statutes "in a manner that authorizes the FDA to impose and NTSO." Answer ¶¶ 2-7. Respondent declined to admit or deny that an "FDA -commissioned inspector conducted an inspection of Parti Expo on [November 13, 2015], as no notification of inspection was provided that day, nor was any notice of violation."<sup>4</sup> Answer ¶ 10. Respondent admits that it has been the subject of two prior CTP Civil Money Penalty ("CMP") actions based on its violations of the Act; and appears to concede that the record is correct "regarding any past violations and previous settlements." Answer ¶¶ 12-14.

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<sup>4</sup> I note a discrepancy between Respondent's assertion that it did not receive any notice of violation, and Respondent's later assertion that on December 2, 2015, it issued a response to CTP's November 18, 2015 Notice of Compliance Check Inspection. *See* Answer at 4; *See also* Parti Expo Letter to FDA ("Respondent's Ex. B").

### 1. Parties' Contentions and Evidence

Respondent raises several arguments in defense to CTP's allegations.<sup>5</sup> Respondent states that it "promptly responded to this matter" after receiving CTP's Notice of Compliance Check inspection. *See* Answer at 4<sup>6</sup>; *see also* Parti Expo Letter to FDA ("Respondent's Ex. B"). Respondent argues that "the temporal proximity [from November 18, 2015, the date of the Notice of Compliance Check inspection, and September 23, 2016, the date of service of CTP's Complaint], has made Complainant's case less tenable." *See* Answer at 4.

Respondent denies that the violation occurred because no one who works at Parti Expo matches the description in Inspector Shafto's report. *Id.* Inspector Shafto described the employee who sold the tobacco products to the minor as male, adult, with black/brown hair. *See* Tobacco Inspection Management System ("TIMS Form, CTP Ex. 17"); Narrative Report, CTP Ex. 18 at 2. Inspector Shafto also stated that the employee wore glasses and had a beard and a mustache. *Id.* Respondent asserts that Parti Expo policies require that "all male employees must be clean shaven with no facial hair." Answer at 4 (emphasis omitted). Respondent asserts that it invited CTP to review surveillance footage based on the date and time of notice and that CTP did not send an agent or representative to view the footage. *Id.* Since also most a year had passed, Respondent no longer has the footage. *Id.* Respondent also argues that it maintains a strict policy along with signs posted all over the establishments requiring its employees to ID every customer prior to selling alcohol or tobacco. *Id.* at 5.

Respondent's main argument is that the current violations did not occur and thus, a 30-day NTSO is inappropriate. Respondent suggests that Inspector Shafto likely made a mistake in the records because he was overworked from "inspect[ing] eleven (11) establishments on the same day that he investigated Parti Expo." *See generally*, Respondent's Post-hearing Brief ¶¶ I-III, VII. Respondent states that it relies heavily on tobacco sales and that an NTSO would irreparably damage the business. *See* Answer at 7. Respondent further states that an NTSO would lead to a reduction in sales for all products, and eventually to a shutdown. *Id.*

CTP's case against Respondent relies on the testimony of Inspector Shafto who accompanied by a confidential state-contracted minor ("Minor 433"), conducted an undercover buy portion of a follow-up compliance check inspection at Parti Expo, on November 13, 2015. Informal Brief of Complainant at 4. As evidence,<sup>7</sup> CTP provided a sworn declaration from Inspector Shafto. *See* Shafto Declaration, CTP Ex. 24. Inspector Shafto is an FDA-commissioned officer with the Michigan Department of Health and Human Services. *Id.* ¶ 2. His duties include conducting undercover inspections to

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<sup>5</sup> The arguments and defenses discussed here are not exhaustive.

<sup>6</sup> Respondent did not number the pages in its Answer.

<sup>7</sup> The evidence discussed in this paragraph is not exhaustive.

determine whether retailers comply with the age and photo identification requirements relating to the sale of tobacco. CTP Ex. 24 ¶¶ 2-3. CTP provided a copy of the Compliance Check Inspection Notice, CTP Ex. 19; Inspector Shafto's Narrative Report of the undercover inspection, Narrative Report, CTP Ex. 18; the TIMS Form, CTP Ex. 17; and a redacted copy of the Minor 433's identification ("ID"), CTP Ex. 5. Finally, Respondent cross-examined Inspector Shafto at the August 17, 2017 hearing. *See* Hearing Transcript at 10-40.

During the August 17, 2017 hearing, Respondent's counsel challenged the integrity of Inspector Shafto's report.<sup>8</sup> For example, he asked whether Inspector Shafto (1) actually observed the transaction between the cashier and the Minor 433; (2) knew whether Minor 433 used a fake ID; (3) knew that the penalty would be an NTSO, before he performed the investigation; (4) requested a receipt or took video footage of the transaction; (5) and (6) took any pictures of the inside the establishment.<sup>9</sup> *See* Hearing Transcript at 15-26, 35-37. Respondent's counsel also questioned Inspector Shafto about whether there was a time lapse between when Minor 433 exited the store and when the Inspector met the minor. *See* Hearing Transcript at 23. Respondent's counsel asked Inspector Shafto about how long after the purchase he created the narrative report. *See* Hearing Transcript at 25-27. Finally, he asked whether Inspector Shafto does any follow-up investigation on the sale after he writes his narrative. *See* Hearing Transcript at 37.

Respondent argues that this case should be dismissed because during the August 17, 2017 hearing, Inspector Shafto failed to recollect key events from the day of the inspection. *See* Respondent's Post-hearing Brief ¶ I. He further argues, *inter alia*, that there is great potential for inaccuracy given the workload and saturation of the market, and that Mr. Atty was not cross-examined. *Id.* at II, VII.

## 2. Findings of Fact

I find that Inspector Shafto testified credibly and comprehensively about his observations during the November 13, 2015 inspection at which he observed Respondent selling tobacco products to Minor 433. *See* Hearing Transcript at 15 -37, 45; Shafto Declaration, CTP Ex. 24; Narrative Report, CTP Ex. 9. I will not recite every detail of Inspector Shafto's testimony but will highlight the points relevant to Respondent's contention that Inspector Shafto's report might have been inaccurate because of his workload and saturation of the market.

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

Q. How long after the sale do you generate a report based off your findings?

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<sup>8</sup> I note that Respondent's counsel asked questions that were outside the scope of Inspector Shafto's Declaration.

<sup>9</sup> This is not an exhaustive list of the questions that Respondent's counsel asked.

A. What do you mean do I generate? What do you mean by "generate a report"?

Q. Okay. Let me go through your statement. "Shortly after the inspection, I recorded the inspection in FDA's Tobacco Inspection Management System and created a narrative report." How long after that purchase do you create this narrative report?

A. It's a matter of minutes that I create the report. Normally, I -- if I have taken all of the pictures of the establishment, I -- and we leave the --and we've attempted the sale, and we leave the establishment and get back to the car, I make sure that the decoy gives me the tobacco product that was confiscated, and then I finish taking pictures if I haven't done them beforehand --

Q. Okay.

A. -- and then drive to a safe location to complete the report. And then --

Q. Okay. And so you don't wait until the end of the day or after your last inspection --

A. Oh, no. No, no, no, no. No.

Q. Okay. So you generate that report right away.

A. Yes.

Q. Is that report part of your -- part of the Compliance Check Action Notice that's given to the establishment?

A. I don't handle what is given to the establishment, so -- but I believe that those reports were sent to the establishment, but I don't do that work. That's not my job.

Hearing Transcript at 26 -27.

Inspector Shafto's testimony is consistent with his declaration that shortly after the inspection, he "recorded the inspection in FDA's Tobacco Inspection Management System ("TIMS") and created a Narrative Report." Shafto Declaration, CTP Ex. 24 ¶ 12. There is no evidence in the record that Inspector Shafto took a detour or conducted another inspection before filing out the TIMS Form. Accordingly, Respondent's contention is speculative.

During the redirect examination conducted by CTP's counsel, Inspector Shafto testified about the accuracy of his reports. This is the relevant excerpt of Inspector Shafto's testimony during the redirect-examination:

Q. You know what, that's fine, you don't have to answer that question. Let me move on. Do you ever make up a sale if it didn't happen?

A. No.

Q. Do you ever record something as happening if it didn't happen?

A. No.

Q. Do you ever write down anything you saw that you didn't see?

A. No.



Q. Okay. So you had mentioned that -- so earlier the question -- there was a question about the cigarettes and where it came from. You are testifying - - you testified that you saw the -- that you saw the minor purchase the cigarettes, and the cigarettes --the minor gave the cigarettes to you, right? The minor took the cigarettes from the store, bought it from the store, and gave it to you --

A. Correct.

Q. -- and you sealed it.

A. Correct.

Q. Okay, so that is your proof that the cigarettes came from Parti Expo's store on that date at that time, correct?

A. That's correct.

Hearing Transcript at 44 -45.

Based on Inspector's Shafto's testimony, I find that the violations occurred as he reported. I also find that Inspector Shafto testified credibly regarding the description of the employee. Respondent failed to support its argument that no employee matches this description. Without some corroborating evidence for example, a written policy that all employees must be clean shaven in effect **during the time period at issue**, or footage of the employee in question on that day, this assertion does not hold water. Moreover, Respondent should have maintained the video footage of the date and time specified in the November 18, 2015 Notice of Compliance Check Inspection.

Respondent has asked that I give Mr. Atty's Statement "proper attention as rebuttal and counter evidence." Respondent's Post-hearing Brief ¶ VII (emphasis omitted). I reiterate that Mr. Atty's statement is not a declaration under oath. *See supra* note 3. The November 15, 2016 APHO contained provisions that set out instructions regarding a party's submission of written direct testimony. *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 perjury for false testimony.**" *See* APHO ¶ 9 (emphasis added); *see also* 21 C.F.R §§ 17.25(a), 17.37(b). Because Mr. Atty's statement does not constitute a written declaration that is signed by the witness under oath, I cannot accord it such weight. CTP was not obliged to cross-examine Mr. Atty. Even if I were to consider Mr. Atty's statement and the fact that CTP did not raise an objection to the statement, the evidence in support of CTP's allegations is overwhelming. Moreover, Respondent's counsel should have complied with the APHO requirement if he wanted Mr. Atty's statement to be accorded the same weight as a sworn declaration.

I find that CTP has provided an abundance of evidence to support its allegation that Respondent (1) sold tobacco products to a Minor 433 on November 15, 2015, 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). I find that Respondent has failed to provide sufficient evidence to rebut CTP's allegation. Respondent had ample opportunity to defend this case. However, Respondent failed to submit corroborating

evidence such as video footage of the employee and transaction; Mr. Atty's written direct testimony under oath to rebut the Inspector Shafto's declaration, and a copy of the policy regarding facial hair that was in place during the time of the inspection.

The facts show that Respondent is a serial violator who settled two prior CMPs. *See* Complaint ¶¶ 12-14. Respondent is aware of the FDA's enforcement program regarding tobacco sales to minors. Moreover, each complaint provides information regarding the relevant statutes and increasing CMP penalties for additional violations, and a link to the guidance regarding CMPs and NTSOs. *See e.g.*, Complaint ¶¶ 2-6. While it is not explicit on how and when an NTSO may occur, there is no requirement that CTP provide explicit notice that an NTSO could occur. I find that Respondent had many interactions with CTP's enforcement program and was provided sufficient notice that repeated violations result in increasingly severe penalties.

The facts as outlined above, establish that Respondent Atty's Parti Expo, Inc. d/b/a Parti Expo 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 tobacco products 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 tobacco product purchasers are younger than 18 years of age.

### **B. 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* CRD Docket Number C-15-744, FDA Docket Number FDA-2014-H-2267; CRD Docket Number C-15-3611, FDA Docket Number FDA-2015-H-2810. Between March 1, 2014 and November 13, 2015, Respondent sold tobacco products to minors on four occasions. *See* Complaint at 1, 13-14. On three of those occasions, Respondent failed to verify by means of photographic identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. *Id.* For the purposes of the instant NTSO action, CTP counted the violations that occurred on July 31, 2014, through November 13, 2015.

The record shows that Respondent has conceded that the past violations occurred. Answer ¶¶ 12-14. 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 such violation in subsequent actions," there

is no basis for questioning whether the current allegations are repeat violations. *Id.*; *see also* Complaint ¶¶ 12-14. Thus, Respondent committed a total of five repeated violations of FDA's tobacco regulations over a 36-month period.

CTP imposed two CMPs on Respondent but the CMPs did not deter Respondent from unlawfully selling tobacco products to minors. CTP now believes that, for Respondent's five repeated violations in less than 36 months, an assessment of a 30-day NTSO is appropriate. *See* Informal Brief of Complainant at 2. Respondent's counsel argues that the NTSO will cause irreparable damage to Respondent's business. *See* Respondent's Post-hearing Brief ¶ IX. He further argues that the burden of proof is so high on the accused and that according to Mr. Atty, who personally reviewed the surveillance footage, "no such sale, took place." *Id.*

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. 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 11. Thus, I find that an NTSO of 30 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. I am not persuaded that the NTSO would severely hinder Respondent Parti Expo'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 two prior CMP actions. In addition to the original violations on March 1, 2014, and the two current violations on November 13, 2015, Respondent has twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and 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(b)(1). *See* Complaint ¶¶ 1, 13-15.

#### 5. *Degree of Culpability*

Based on my finding that Respondent committed the most recent violation 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 it has created a formal policy, to prevent future violations, which is attached to its Answer. *See* Answer at 7; *see also* Parti Expo Tobacco and Liquor Policy. I am not persuaded that Respondent's current effort to implement this policy will be effective. Respondent reportedly established a similar policy in the past, and that did not prevent tobacco violations from recurring subsequently. *See* Informal Brief of Complainant at 11. "Specifically, in [its] answer to the First CMP Complaint, Respondent requested a reduction to the proposed civil money penalty on the basis that [it] had" implemented the policy. *Id.* Because Respondent is a habitual and unremorseful violator of the FDA tobacco regulations, I find that a 30-day NTSO is necessary.

### **VI. Penalty**

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order 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 No-Tobacco-Sale Order 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 Dec. 15, 2016).

### **VII. Conclusion**

For these reasons, I impose a No-Tobacco-Sale Order against Respondent Atty's Parti Expo, Inc. d/b/a Parti Expo, for a period of 30 consecutive calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own

