

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-R-0626)

Complainant

v.

Zoom Mini Mart, Inc.,

Respondent.

Docket No. T-17-2001

Decision No. TB2441

Date: February 14, 2018

**INITIAL DECISION**

I hereby impose a No-Tobacco-Sale Order against Respondent, Zoom Mini Mart, Inc., for a 30 consecutive calendar day period, for six 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, Zoom Mini Mart, Inc., located at 14545 Plymouth Road, Detroit, Michigan 48227, for six 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 cigarettes or smokeless tobacco to minors and failed to verify that the cigarette or smokeless tobacco 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 Zoom Mini Mart, Inc. 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 of cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)(1),<sup>1</sup> on December 31, 2013, July 9, 2014, April 18, 2015, and March 10, 2016; and (2) One original violation and three 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 those same dates. *See* Complaint ¶¶ 1, 6, 9-12; *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.

## 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 14545 Plymouth Road, Detroit, Michigan 48227, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management.

On March 2, 2017, Respondent, through counsel, timely filed a Response to Administrative Complaint for No-Tobacco-Sale-Order ("Answer"). On March 7, 2017, I issued an Acknowledgment and Pre-Hearing Order ("APHO") that set out the deadlines<sup>2</sup> for the parties' submissions in this case and issued informal briefs for the parties to complete and submit.

On June 13, 2017, CTP timely filed its pre-hearing exchange. CTP's pre-hearing exchange included an informal brief ("Informal Brief of Complainant"), a list of proposed witnesses and exhibits, and twenty-one (21) numbered exhibits. CTP's exhibits included the declaration of one witness. On July 3, 2017, Respondent filed its pre-hearing exchange. Respondent's pre-hearing exchange included an informal brief ("Respondent's Informal Brief"), and a list of proposed witnesses and exhibits. However, Respondent failed to upload any sworn witness statements or any of the proposed exhibits.

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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> On May 24, 2017, the CTP filed a Joint Motion to Extend Deadlines. On May 26, 2017, I issued an order extending the APHO deadlines as requested in the Joint Motion to Extend Deadlines.

### **Pre-Hearing Conference**

On August 3, 2017, I held a pre-hearing conference in this case. I explained that the purpose of a hearing was to admit the parties' exhibits and to allow for the cross-examination and re-direct of any witnesses who have provided sworn testimony in exchanges. I noted that while Respondent filed a list of proposed witnesses and exhibits, Respondent neither filed the direct written testimonies of the proposed witnesses nor copies of the proposed exhibits. I informed the parties that Inspector Justin Bishop was the only witness who could appear for cross-examination at the hearing as only CTP included written direct testimony, under oath, by the exchange date. Respondent's Counsel stated that he had submitted copies of the proposed exhibits and witness testimony, did not know why it was not in the file, and communicated his desire to file a motion regarding the Respondent's proposed witnesses and exhibits. Respondent's Counsel also communicated his desire to cross-examine CTP's Inspector Justin Bishop.

On August 4, 2017, I issued an Order to Show Cause Why Respondent's Witnesses and Exhibits were not Submitted in Accordance with C.F.R. §§17.25 (a), 17.37(b) ("OSC"). In the OSC, I allowed Respondent until August 14, 2017, "to show cause: (1) why copies of proposed exhibits and written declarations of any proposed witness testimony were not furnished, and (2) why the proposed exhibits that Respondent uploaded were not properly marked, as provided in the March 3, 2017 Order." I also stated that "Respondent must demonstrate that **extraordinary circumstances** prevented compliance with the March 3, 2017 Order and 21 C.F.R. §§ 17.25(a), 17.37(b)."<sup>3</sup> Finally, I allowed CTP until August 29, 2017, to respond to Respondent's motion.

### **Respondent's Motion**

On August 14, 2017, Respondent filed a Motion for Leave to Call Witnesses and Have Exhibits Admitted at the Hearing ("Respondent's Motion"). Respondent attached twelve (12) proposed exhibits, including a Sworn Statement of Nabil Hizam, with its motion.<sup>4</sup> On August 29, 2017, CTP filed an Opposition to Respondent's Motion for Leave to Call Witnesses and Have Exhibits Admitted at the Hearing. After a careful review of the parties' submissions, I found that Respondent's Motion was not responsive to my Order to Show Cause because it failed to demonstrate that extraordinary circumstances prevented Respondent from complying with the APHO provisions ¶¶ 6, 9-10, and 21 C.F.R. §§ 17.25(a), 17.37(b). Accordingly, on September 8, 2017, I issued an Order Denying Respondent's Motion for Leave to Call Witnesses and Have Exhibits Admitted at the Hearing and Scheduling In-Person Telephone Hearing ("September 8, 2017

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<sup>3</sup> The August 4, 2017 OSC refers to the March 3, 2017 Order through inadvertent typographical error. Based on the language in the August 4, 2017 OSC the document referred to is clearly the March 7, 2017 APHO.

<sup>4</sup> Respondent failed to properly mark all the proposed exhibits. See APHO ¶ 6.

Order”). In that same order, I noted that Inspector Justin Bishop was eligible to appear at the hearing and Mr. Nabil Hazim was not eligible to appear at the hearing.

### **In Person Telephone Hearing**

On November 7, 2017, I held a hearing in this case. During the hearing, I admitted CTP’s exhibits numbered 1 through 21. *See* Hearing Transcript at 8. Respondent’s Counsel cross-examined Inspector Bishop. *See* Hearing Transcript at 9-14. CTP’s counsel declined to conduct a redirect examination of Inspector Bishop. *See* Hearing Transcript at 14. On November 29, 2017, I issued an Order informing the parties that the Court had received the transcript of the hearing, and set the deadline for the parties’ post-hearing brief submissions as December 28, 2017. CTP filed a post-hearing brief (“CTP’s Post-hearing Brief”) and Respondent filed a post-hearing brief (“Respondent’s Post-hearing Brief”). I now render my decision.

### **III. Issues**

- A. Whether Respondent Zoom Mini Mart, Inc. sold cigarettes or smokeless tobacco to a minor, and failed to verify that the cigarette or smokeless tobacco purchaser was of sufficient age, on March 10, 2016, 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. § 333(f)(9). The sale of cigarettes or smokeless tobacco 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. Allegations, Parties’ Contentions, and Findings of Fact**

CTP alleges that Respondent committed six repeated violations of the Act and its implementing regulations over a 36-month period. *See Complaint* at ¶ 1. CTP identified Respondent’s original violations and Respondent’s repeated violations of those particular regulations that occurred within a specified 36-month period after the original violations. *Id.* ¶ 1, note 1; *see also id.* ¶ 1 (table).

CTP alleged that at approximately 6:13 p.m. on March 10, 2016, at Respondent’s business establishment, 14545 Plymouth Road, Detroit, Michigan 48227, 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* ¶ 6; *see Informal Brief of Complainant* at 4. The inspector also documented that staff failed to

verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. *Id.*

### *1. Parties' Contentions and Evidence*

Respondent denied the allegations at the outset, but now admits the allegations in its post-hearing final brief. In its Answer, Respondent denied the current and previous allegations stated in the Complaint as “untrue.” Answer ¶¶ 1-4, 6, 9-12. Respondent asserts that CTP is seeking an NTSO for violations pre-dating the adoption of the NTSO sanction as a penalty. *Id.* ¶ 12. Thus, Respondent denies that an NTSO is appropriate “for the reason that the regulation providing for [an NTSO] was adopted after all prior CMP violations.” Answer ¶ 15. Respondent raised seven affirmative defenses in its Answer. *See* Answer Affirmative Defenses ¶¶ 1-7. First, Respondent challenged the total number of alleged violations and asserted that CTP’s method of counting the violations is contrary to the legislative intent of the Act and violates Respondent’s substantive due process. *Id.* ¶¶ 1-5. Then, Respondent reiterates that CTP is applying the NTSO retroactively by including offenses that allegedly occurred prior to the adoption of the regulation. *Id.* ¶ 6. Finally, Respondent asserts that it was not obliged to check the identification of the minor during the alleged improper sale because the minor was accompanied by a person over the age of 26 years. *Id.* ¶ 7.

Respondent, in subsequent briefs, appears to abandon some of the arguments and defenses asserted in its Answer. *See* Respondent’s Informal Brief; Respondent’s Post-Hearing Brief. Respondent denies that the March 10, 2016 sale to a minor and failure to verify violations occurred because “an employee, who was subsequently dismissed . . . maintains that the cigarettes were purchased at the directions of a male accompanying the minor hired by CTP.” Respondent’s Informal Brief ¶¶ 3-4. Respondent asserts that an NTSO is inappropriate because the violations were “a result of a renegade employee who failed to do as he was trained.” *Id.* ¶ 5. Respondent further asserts that its management provides training to its staff, and posted signs “throughout the building stressing that minors are not to buy tobacco.” *Id.* Respondent notes that a point of sales system requires the clerk to ask for a birthdate before tobacco product sales. *Id.* Respondent asserts that its establishment is one of three that are managed by Mr. Nabil Hizam, and that the three gas stations participate in the City of Detroit Green Light Program, which requires participants to invest in cameras that are monitored by the Detroit Police Department. *Id.* Respondent further asserts that a video shows that within thirty minutes of the current alleged violations, there was a similar attempt to purchase tobacco at another store also managed by Mr. Hizam. *Id.* Respondent asserts that the other undercover buy attempt was unsuccessful. *Id.* Respondent then concludes that CTP was focused on this particular merchant and that the agent clearly drove “20 miles from one store to the other in an attempt [to] harass the merchant.” *Id.*

CTP's case against Respondent relies on the testimony of Inspector Bishop who accompanied by a confidential state-contracted minor ("Minor 502"), conducted an undercover buy portion of a follow-up compliance check inspection at Zoom Mini Mart, Inc., on March 10, 2016. Informal Brief of Complainant at 4-5. As evidence to support its current allegations,<sup>5</sup> CTP provided a sworn declaration from Inspector Bishop. *See* Bishop Declaration, CTP Ex. 21. Inspector Bishop is an FDA-commissioned officer with the State of Michigan Department of Health and Human Services. *Id.* ¶ 2. His duties include conducting undercover inspections to determine whether retailers comply with the age and photo identification requirements relating to the sale of tobacco. CTP Ex. 21 ¶¶ 2-3. CTP also provided a copy of the Compliance Check Inspection Notice, CTP Ex. 18; Inspector Bishop's Narrative Report of the March 10, 2016 undercover inspection, Narrative Report, CTP Ex.17; the Tobacco Inspection Management System ("TIMS Report"), CTP Ex. 16; and a redacted copy of the Minor 502's identification ("ID"), CTP Ex. 5. Finally, Respondent cross-examined Inspector Bishop at the November 7, 2017 hearing. *See* Hearing Transcript at 9-14.

During the November 7, 2017 hearing, Respondent's Counsel asked questions that were outside the scope of Inspector Bishop's declaration. For example, he asked about another inspection that Inspector Bishop allegedly conducted before coming to Respondent's store.<sup>6</sup> *See* Hearing Transcript at 10-11. Respondent's Counsel also questioned Inspector Bishop about other attempts to purchase cigarettes at Respondent's facility prior to March 10, 2016. *See id.* at 11-12. I sustained CTP's objections to these questions on the grounds that such evidence is irrelevant to the instant case. *See id.*

Finally, Respondent's Counsel communicated his intent to make a record of some issues. *Id.* at 14. Respondent's Counsel informed the court that he had a witness present "who would testify about mitigating factors related to the operation of the store and the training." Hearing Transcript at 15. He also informed the court that though he had named the witness previously, he did obtain her sworn statement. *Id.* at 15. I ruled that the proposed witness could not testify during the hearing as her sworn statement was not submitted prior to the exchange date as required by the APHO. *Id.* Respondent's Counsel brought up my ruling, on his August 14, 2018 motion, denying him leave to have the exhibits admitted at the hearing. *Id.* I reiterated that "they were not marked as exhibits nor were they submitted to The Court marked as exhibits by the exchange date." *Id.* at 15-16. I informed Respondent's Counsel that he may argue mitigating circumstances in his post-hearing briefs pursuant to 21 C.F.R. § 17.34. *Id.* I also clarified that he "may make reference to the case documents in the administrative record although they are not exhibits." *Id.*

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<sup>5</sup> The evidence discussed in this paragraph is not exhaustive.

<sup>6</sup> This is not an exhaustive list of the questions that Respondent's Counsel asked.

Respondent in its post-hearing brief admits that the March 10, 2016 violations occurred. *See* Respondent's Post-Hearing Brief at 2. I find that Respondent's main argument is that an NTSO is inappropriate because the violations occurred because of a renegade employee. *See id.* at 3.

CTP in its post-hearing brief answered Respondent's argument about the other store allegedly being inspected by this inspector on the same day and the sale being rejected. Specifically, CTP contends that "the training and efforts of Respondent at the other location, even if true and supported by admissible evidence, did not stop Respondent from selling a tobacco product to a minor and failing to verify the purchaser's age by means of photographic identification on March 10, 2016, at the 14545 Plymouth Road location." CTP's Post-hearing Brief at 3. CTP also asserts that the happenings at another store are not relevant to the current alleged violations. *See id.*

## 2. Findings of Fact

I find that Inspector Bishop testified credibly about his observations during the March 10, 2016 inspection at which he observed Respondent selling tobacco products to Minor 502. *See* Hearing Transcript at 12 -14; Bishop Declaration, CTP Ex. 21 ¶¶ 7-11; *see also* Narrative Report, CTP Ex. 17; TIMS Report CTP Ex. 16. During the cross-examination, Respondent's Counsel failed to rebut any of Inspector Bishop's assertions regarding the March 10, 2016 violations. As mentioned above, Respondent's Counsel attempted to elicit testimony about an alleged inspection that Inspector Bishop conducted at another facility prior to the March 10, 2016 inspection:

Respondent's Counsel: . . . Mr. Bishop, you arrived at the Zoom Mini Mart at 6:13 p.m. on March 10, 2016; isn't that right?

A. Correct.

Respondent's Counsel: Immediately prior to this you were at a gas station located at 11030 Morang in Detroit; isn't that right?

CTP: I'm going to object, Your Honor, on the grounds that any inspections unrelated to the establishment at issue in this case are irrelevant to the issues in this case.

Respondent's Counsel: Well, in response it is relevant because this is another facility that's managed by the same management. And the evidence will show that attempt to purchase cigarettes were rejected. This is what we've been arguing from the beginning that there have been dramatic efforts made by the facility, indeed all of the three facilities managed by my client. And instead of this being received it's being rejected and my client's being silenced in an opportunity to provide mitigating circumstances.

CTP: Your Honor . . . again. I'm going to object to counsel's testimony and attempt to get testimony in this case which has been ordered it's not

allowed to have. But reiterate my objection that this case is factually about a sale of tobacco products at a facility located at 14545 Plymouth Road in Detroit, Michigan. And any sales or non-sales by respondent at any other locations are irrelevant to whether the sale occurred as alleged in the complaint.

THE COURT: Okay. And I sustain that objection at this time.

Respondent's Counsel: Now, Mr. Bishop, you made other attempts to purchase cigarettes at this facility prior to March 10, 2016; isn't that true?

CTP: Excuse me. I'm sorry. I have to object again because Mr. Bishop is here to testify about what happened on March 10th, 2016, as alleged in the complaint. And his observations on that day are what his declaration is about, his sworn declaration. And so anything outside of that would be outside of the scope of his declaration and also irrelevant to the issues in this case.

Respondent's Counsel: . . . One of the issues that this Court has to determine is whether there are mitigating circumstances. And while the petitioner would like to limit evidence to what they want the tribunal to hear I don't think it stops us from trying to ascertain whether there were other attempts that were rejected.

THE COURT: I'm going to have to sustain the objection.

Hearing Transcript at 10 -11.

I reiterate that this line of questioning is not relevant to the issues before me, which is whether Respondent Zoom Mini Mart, Inc. sold cigarettes or smokeless tobacco to a minor and failed to verify that the cigarette or smokeless tobacco purchaser was of sufficient age, on March 10, 2016, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i). Other than a denial in its Answer, Respondent has failed to provide evidence that rebuts CTP's evidence in support of its allegations that on March 10, 2016, Respondent sold cigarettes or smokeless tobacco to Minor 502, and that Respondent failed to verify that Minor 502 was of sufficient age.

My March 7, 2017 APHO contained provisions that set out instructions regarding a party's preparation of proposed exhibits, and submission of written direct testimony. *See* APHO ¶¶ 6, 9-10. I do not consider Mr. Hizam's statement to be a proper rebuttal because Respondent's Counsel failed to submit it and other exhibits in accordance with C.F.R. § 17.25 (a), 17.37(b). Respondent's Counsel failed to provide good cause, thus, I excluded the documents as evidentiary exhibits in this case. *See* September 8, 2017 Order; Hearing Transcript at 15-17. Even if I were to consider Mr. Hizam's statement, he appears to concede that the March 10, 2016 violations occurred. *See* Hizam Declaration ¶ 15 (stating "[t]he incident involved in this case was caused entirely by a clerk that ignored his training.") Furthermore, Respondent in its post-hearing brief clearly concedes that the March 10, 2016 violations occurred. *See* Respondent's Post-Hearing

Brief at 2 (“On March 10, 2016 the Center for Tobacco Products utilized an undercover confidential state-contracted minor to conduct a compliance check at the location. The undercover minor was accompanied by FDA commissioned inspector Justin J. Bishop. The undercover minor purchased a Newport box 100s cigarette product from a store clerk.”) Accordingly, I find that the violations occurred as Inspector Bishop reported and alleged in the Complaint.

I find that CTP has provided an abundance of evidence to support its allegation that Respondent (1) sold cigarettes or smokeless tobacco to Minor 502 on March 10, 2016, and (2) failed to verify that the cigarette or smokeless tobacco 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.

The facts show that Respondent is a repeated violator who settled two prior CMPs. *See* Complaint ¶¶ 8-9. Respondent is aware of the FDA’s enforcement program regarding cigarettes or smokeless 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.*, Complaint ¶¶ 2-3.

The facts as outlined above, establish that Respondent Zoom Mini Mart, Inc., 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.

### **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 repeated violator of FDA’s tobacco regulations. Respondent has been the subject of two prior CMP actions. *See* CRD Docket Number C-15-862, FDA Docket Number FDA-2015-H-0064; CRD Docket Number C-15-3445, FDA Docket Number FDA-2015-H-2682. Between December 31, 2013 and March 10, 2016, Respondent sold cigarettes or smokeless tobacco to minors and 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, on four occasions. *See* Complaint at ¶¶ 1 (Table), 6, 9-11.

The record shows that Respondent has conceded that the current violations occurred. *See* Respondent's Post-Hearing Brief at 2. 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. *See also* Complaint ¶¶ 9-10. Thus, "Respondent committed six repeated violations of FDA's tobacco regulations within the 36-month period July 9, 2014, through March 10, 2016." *See id.* ¶ 1.

CTP states the two previous CMPs did not deter Respondent from unlawfully selling tobacco products to minors. *See* Complainant's Post-Hearing Brief at 5-6. CTP maintains that for Respondent's six repeated violations within 36 months, an assessment of a 30-day NTSO is appropriate. *See id.* Respondent's Counsel argues for mitigation of the NTSO because Respondent has provided training to all its employees, posted signs in its stores prohibiting the sale of tobacco products to minors, and implemented a point of sales system that requires a birthdate to be entered for tobacco sales. *See* Respondent's Post-hearing Brief at 3-4. Respondent's Counsel also highlighted Respondent's involvement in various local programs within the community. *Id.* at 4. Respondent's Counsel alleges that CTP is biased against Respondent and is "focusing on this merchant, rather than a geographic area." *Id.* Finally, Respondent's Counsel asserts that "the unsuccessful attempt to buy tobacco products at the other store shows that the training and efforts of the Respondent's Mr. Nabil Hizam, is working." *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*

The Respondent admits that a "renegade" employee failed to verify the age of Minor 502 by means of photo identification and sold cigarettes to a minor on March 10, 2016. Therefore, I find that Respondent committed three (3) violations of selling cigarettes or smokeless tobacco to minors, and three (3) violations of failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. Respondent's repeated inability to comply with federal tobacco regulations is serious in nature. Accordingly, I find that 30-day NTSO 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).

## 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 Zoom Mini Mart, Inc.'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 . . . ." *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*

Respondent is a repeated violator of FDA's tobacco regulations prohibiting the sale of cigarettes or smokeless tobacco to minors. This is the first NTSO action against Respondent for violations of the Act and its implementing regulations. As noted above, in addition to the original violations on December 31, 2013, and the two current violations on March 10, 2016, Respondent has previously 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), and twice violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). *See* Complaint ¶¶ 1, 6, 9-11.

## 5. *Degree of Culpability*

Based on the Respondent's admission and the preponderance of the evidence, which shows the Respondent committed the two most recent violations in the current complaint, I hold it fully culpable for six repeated violations of the Act and its implementing regulations.

## 6. *Additional Mitigating Factors*

In its post-hearing brief, Respondent eventually admitted the violations occurred. In its briefs, Respondent indicates that it posted multiple signs within the store. Respondent's briefs also allegedly state there is employee training and a point of sales system that prompts the clerk to ask for a birthdate before tobacco product sales, and notes Respondent's involvement in various local programs within the community. While I commend Respondent's efforts, I do not find any mitigating factors. Although Respondent has argued bias by CTP, Respondent has failed to provide any evidence of

bias against Respondent's establishments. I am not persuaded that Respondent's efforts have been effective for this store. As previously mentioned, Respondent's training and policies in another location are not relevant to the March 10, 2016 documented violations for this location. Additionally, this is the sixth 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. Penalty**

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for six (6) 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 December 15, 2016).

Based on the foregoing reasoning, I find a penalty of a NTSO for 30 days to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

## **VII. Conclusion**

For these reasons, I impose a No-Tobacco-Sale Order against Respondent Zoom Mini Mart, Inc., 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/  
Wallace Hubbard  
Administrative Law Judge