

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-6876)

Complainant,

v.

Stowers Enterprises, Inc.  
d/b/a BP,

Respondent.

Docket No. T-18-668

Decision No. TB3389

Date: December 31, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) of \$5,591 against Respondent, Stowers Enterprises, Inc. d/b/a BP, located at 807 West Atkinson Avenue, Milwaukee, Wisconsin 53206, for five 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. Specifically, CTP alleges that BP violated the Act by impermissibly selling covered tobacco products to minors and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. For the reasons discussed below, I find in favor of CTP and impose a \$5,591 CMP against Respondent.

**I. BACKGROUND AND PROCEDURAL HISTORY**

CTP began this matter by serving an administrative complaint (Complaint) seeking a \$5,591 CMP on Respondent, at 807 West Atkinson Avenue, Milwaukee, Wisconsin

53206, and by filing a copy of the Complaint with the Departmental Appeals Board (DAB). *See* DAB E-File Docket (Dkt.) Nos. 1-1b.

On January 16, 2018, Respondent, represented by counsel, timely filed an Answer and motion for extension requesting additional time within which to file an Amended Answer. Dkt. No. 3. I granted Respondent's motion and provided Respondent until February 15, 2018, to file an Amended Answer. Dkt. No. 4. On January 26, 2018, Respondent served CTP with a Discovery Demand for production of documents, seeking two categories of documents. Dkt. No. 6a. On February 5, 2018, CTP filed a Motion for a Protective Order concerning the document requests. Dkt. No. 6. Respondent did not file a response to CTP's motion. On February 26, 2018, CTP filed a Memorandum of Law in support of its Motion for a Protective Order and six attachments (CTP Attach. 1-6) in support thereof, including a Privilege Log (CTP Attach. 1). Dkt. Nos. 8-8f.

On March 13, 2018, I granted CTP a limited protective order. Dkt. No. 9. Accordingly, CTP was not required to produce unredacted copies of documents responsive to Respondent's requests. *Id.*

On March 13, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for discovery and the parties' pre-hearing exchanges. Dkt. No. 10. On 34 4, 2018, CTP timely filed a pre-hearing brief, a list of proposed witnesses and exhibits, and 14 exhibits (CTP Exhibits (Exs.) 1-14) including the written direct testimony of two proposed witnesses, Senior Regulatory Counsel Laurie Sternberg and Inspector Jason Laurin (CTP Exs. 3-4). Dkt. Nos. 12-12o. On June 25, 2018, Respondent filed a pre-hearing brief, (Dkt. No. 14a) and on August 6, 2018, Respondent filed an amended list of proposed witnesses and exhibits, which included five exhibits (Respondent (Resp.) Exs. 1-5) four proposed witnesses, and written direct testimony of the four proposed witnesses. Dkt. Nos. 20-20e. Respondent's proposed witnesses included: Benny Wilson, Respondent's stocking clerk; Isaiah Wilson, Respondent's cashier; Steven Gabrish, a private investigator retained by Respondent; and Diane Stowers, Respondent's owner. *Id.*

On August 8, 2018, I held a pre-hearing conference in this case. *See* Dkt. No. 22. I explained to the parties that the purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination of witnesses. I further explained that I must determine whether Respondent is liable for the violations alleged in the complaint as well as the appropriate penalty. At the pre-hearing conference, Respondent waived its right to cross-examine CTP's proposed witnesses. Consequently, CTP indicated that it did not wish to cross-examine Respondent's proposed witnesses. Both parties indicated that they did not see the necessity for an in-person telephone hearing and agreed to a decision based on the documents entered into the record.

After I informed the parties that I would make a decision based on the evidence in the record, both parties requested the opportunity to submit additional evidence. I informed the parties that I would allow them to submit additional evidence and file any objections to an opposing party's additional evidence. Dkt. No. 22.

On August 13, 2018, CTP filed two additional exhibits (CTP Exs. 15-16), which included a supplemental declaration of Inspector Jason Laurin and Minor A's redacted identification. Respondent did not file any objection to these exhibits. The parties were given the opportunity to submit final briefs with any arguments they wished for me to consider. On October 5, 2018, Respondent filed its final brief (Resp. Final Brief). CTP did not file a final brief. As the briefing period is over, I now render my decision.

## II. ISSUES

- A. Whether Respondent sold covered tobacco products to a minor and failed to verify by means of photographic identification that the covered tobacco products purchaser was of sufficient age on November 30, 2017, in violation of 21 C.F.R. § 1140.14(b)(1) and (b)(2)(i); and
- B. If so, whether the CMP amount of \$5,591 sought by CTP is appropriate.

## III. ANALYSIS

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. 21 C.F.R. § 17.33(b). The U.S. Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Prods. of Cal., Inc. v. Constr. Laborers*, 508 U.S. 602, 622 (1993).

### A. Violations

CTP determined to impose a CMP against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. 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). FDA and its agency, CTP, may seek CMPs from 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 covered 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(b)(1) and (b)(2).

In its Complaint, CTP alleges that Respondent BP committed five violations of the Act and its implementing regulations within a 36-month period. Dkt. No. 1 ¶ 1. Specifically, CTP alleges that on November 30, 2017, Respondent sold covered tobacco products to a minor and failed to verify the photographic identification of the minor. CTP further alleges that Respondent previously admitted to three<sup>1</sup> violations of regulations found at 21 C.F.R. pt. 1140. *Id.* ¶¶ 9, 11-12. In settling the prior complaint, Respondent not only admitted the violations occurred but also waived the right to contest the violations in the future and stated that it understood that the admitted violations may be counted in determining the total number of violations for future enforcement actions. *Id.* ¶ 12; *see also* Dkt. No. 12 at 2-3. Accordingly, the only issue before me is whether Respondent sold covered tobacco products to a minor and failed to verify the photographic identification of the minor on November 30, 2017, in violation of 21 C.F.R. § 1140.14(b)(1) and (b)(2)(i), as alleged in the Complaint.

CTP's case against Respondent rests on the testimony of Ms. Sternberg and Inspector Laurin, supported by corroborating evidence. *See* CTP Exs. 3-4. Ms. Sternberg testified that the Swisher Sweets cigars purchased during the November 30, 2017 inspection were manufactured or processed for commercial distribution at facilities in Kentucky and West Virginia. CTP Ex. 3 ¶¶ 7-8. The manufacturer of Swisher Sweets cigars does not have production facilities in Wisconsin, where the covered tobacco products were purchased. *Id.* ¶ 9. Respondent did not challenge Ms. Sternberg's testimony and did not dispute that Respondent held Swisher Sweets cigars for sale at its business establishment on November 30, 2017. *See* Dkt. Nos 14a, 26a. Accordingly, I find that Respondent's establishment received Swisher Sweets cigars in interstate commerce and held them for sale on November 30, 2017, after shipment in interstate commerce.

Inspector Laurin is an FDA-commissioned officer for the state of Wisconsin whose duties include performance of undercover buy (UB) inspections to determine a retailer's compliance with the age and photo identification requirements relating to the sale of tobacco products. CTP Ex. 4 ¶¶ 3-4. The UB inspections are conducted with trained minors by providing "direct field oversight of the minors to ensure that they follow FDA inspection protocol." *Id.* ¶ 5.

Inspector Laurin testified that on November 30, 2017, he conducted such an inspection of Respondent's establishment, located at 807 West Atkinson Avenue, Milwaukee, Wisconsin 53206. CTP Ex. 4 ¶ 8. Minor A, whose date of birth is March 24, 2000, was 17 years old at the time the minor accompanied Inspector Laurin on the November 30, 2017 inspection. *See* CTP Ex. 5. Minors in the tobacco program are trained to carry

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<sup>1</sup> Two violations were documented on October 25, 2016, and two on May 31, 2017 (sale to a minor and failure to verify date of birth). Dkt. No. 1 ¶ 11. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and subsequent violations as separate individual violations.

photographic identification with them during an inspection and are instructed to tell the truth if they are asked about their age or whether they have identification. CTP Ex. 4 ¶ 6. Before the inspection, Inspector Laurin confirmed that Minor A was under the age of 18, that Minor A possessed photographic identification showing her actual date of birth, and that Minor A did not have any tobacco products in her possession. CTP Ex. 4 ¶ 8. I note that Inspector Laurin's June 4, 2018 written direct testimony does not reflect Minor A's gender. *Id.* On August 13, 2018, CTP submitted a partially redacted copy of Minor A's driver's license. The driver's license documents that Minor A is female. CTP Ex. 16.

Inspector Laurin testified that he parked his car near Respondent's establishment and remained in the vehicle during the inspection, because he felt his presence would compromise the undercover nature of the inspection. CTP Ex. 4 ¶ 9. Inspector Laurin had an unobstructed view of Minor A exiting the vehicle, entering Respondent's establishment, exiting the establishment less than five minutes later, and immediately returning to the vehicle. CTP Ex. 4 ¶¶ 9-10. Inspector Laurin testified that upon entering the vehicle, Minor A handed him a package of Swisher brand cigars. CTP Ex. 4 ¶ 10.

Inspector Laurin testified that Minor A reported to him that during the inspection, Minor A was able to purchase a package of cigars from an employee at Respondent's establishment. CTP Ex. 4 ¶ 10. Minor A also reported to Inspector Laurin that prior to the purchase, the employee did not ask for Minor A's identification, Minor A did not present any identification to the employee, and the employee did not provide Minor A with a receipt after the purchase. *Id.*

Inspector Laurin processed the evidence in accordance with standard procedures. CTP Ex. 4 ¶ 10. Shortly after the inspection, Inspector Laurin recorded the inspection in the FDA's Tobacco Inspection Management System (TIMS) and created a Narrative Report. *Id.* ¶ 11. CTP corroborated Inspector Laurin's testimony by offering as evidence photographs that Inspector Laurin made of the cigars that Minor A purchased on the date in question. CTP Exs. 8-9. CTP also submitted the TIMS form and Narrative Report created by Inspector Laurin shortly after the inspection. CTP Exs. 6-7.

Respondent filed an Answer, informal brief, and final brief. *See* Dkt. Nos. 3, 14a, and 26a. In its filings, Respondent argues that CTP should not hold the owner responsible for the actions of others. In Respondent's informal brief filed on June 25, 2018, Respondent also contends that Minor A "[was] the only CTP witness to the sale and his statement is the sole factual basis for the Complaint." Dkt. No. 14a, at 2. Further, Respondent argues that Inspector Laurin was not present at BP at the time of the alleged purchase and that he could not see the purchase from outside the store. *Id.* In its informal and final briefs, Respondent challenges the integrity of the undercover inspection by attacking the credibility of Minor A.

Respondent presents a different scenario of what occurred in the store on November 30, 2017, by submitting a statement from a private investigator who represents that he interviewed two employees and the store's owner on February 15, 2018. Resp. Ex.3, Dkt. No. 20c. The investigator's detailed report discusses information that the investigator asserts that he received during interviews with employees Benny and Isaiah Wilson concerning the events of November 30, 2017. The report includes a lengthy explanation of a juvenile's attempt to purchase a "blunt cigar" and describes in detail the interaction between the juvenile and the cashier, the juvenile's behavior, and the juvenile's solicitation of another customer to buy the cigar.

Respondent also submitted the written statements of Benny and Isaiah Wilson, the employees on duty on the evening of November 30, 2017. Resp. Ex. 1 and 2. In a handwritten statement dated December 27, 2017, Isaiah Wilson testified that "a young man came to buy a Tobago [sic] item[.] I told him he needed A ID. He left the Register Went back by coolers." Resp. Ex. 2.

Additionally, in a handwritten statement dated December 27, 2017, Benny Wilson, who was working in the store at the time of the inspection testified that "young man walk [sic] in and ask Chasher [sic] for a blunt and Chasher [sic] ask for I.d." The testimony continues, "the young man got mad and started curseing [sic]." Mr. Wilson further stated that afterwards, "...the young man walk [sic] back by the cooler and ask [sic] a man who was back there and that man bought the blunt for him." Resp. Ex. 3.

Unlike the more comprehensive statement prepared by the private investigator, the statements submitted by these witnesses contain no information about the juvenile's specific comments while in the store, nor do they include a physical description of the ethnicity or age of the man at the back of the store.

I note that Isaiah and Benny Wilson repeatedly refer to the minor as "he," or "him," in not only their December 27, 2017 statements that were prepared less than a month after the November 30, 2017 incident, but also in their August 6, 2018 sworn declarations. Clearly at no point did Isaiah and Benny Wilson describe the minor attempting to purchase a tobacco product during the relevant time period as female.

Despite Respondent's arguments, I do not find the testimony of Isaiah and Benny Wilson to discredit the testimony of Inspector Laurin. Inspector Laurin testified credibly and comprehensively about his observations during the November 30, 2017, inspection.<sup>2</sup> I also find Inspector Laurin's testimony is corroborated by photographic proof that Respondent sold a package of Swisher Sweets cigars to Minor A on November 30, 2017,

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<sup>2</sup> While it is undisputed that Inspector Laurin did not directly witness the alleged transactions on November 30, 2017, the regulations do not require such a direct eyewitness.

in violation of 21 C.F.R. § 1140.14(b)(1). Inspector Laurin's testimony establishes that Minor A did not have covered tobacco products in her possession before entering the store and had covered tobacco products upon leaving the establishment. Consequently, the only reasonable inference that I can draw from the evidence is that Minor A purchased covered tobacco products in the store. Minor A's statement to Inspector Laurin further confirms that during the inspection, Minor A was able to purchase a package of Swisher Sweets cigars from an employee at Respondent's establishment.

Witnesses Isaiah and Benny Wilson consistently refer to the minor as male, even though Minor A was actually female. *See* CTP Exs. 15, 16. Although CTP initially followed its standard practice of redacting the gender of the minor, once it became clear that Respondent's arguments were focused on attacking the credibility of a minor who Respondent's witnesses thought was male, CTP proffered an exhibit showing the gender of Minor A as specified on her state driver's license. *Compare* CTP Exs. 5 and 16. Inspector Laurin also testified that Minor A is female. CTP Exs. 15.

I give the private investigator's report (Resp. Ex. 3) little weight. The private investigator compiled the information contained in the report on or after February 15, 2018, for events that occurred on November 30, 2017. CTP initiated its Complaint on December 20, 2017 (Dkt. No. 1) and Respondent requested a hearing in its January 16, 2018 Answer (Dkt. No. 3). Therefore, it is reasonable that the investigator most likely prepared the report in part in anticipation of a hearing in this matter. Furthermore, the information provided in the report is primarily hearsay. Fed. R. Evid. 801. I find the December 27, 2017 hand-written statements of Isaiah and Benny Wilson to be the most reliable account offered by these two witnesses.

However, under 21 C.F.R. Part 17, the Administrative Law Judge determines the admissibility of evidence and has discretion to apply the Federal Rules of Evidence when deemed appropriate. Therefore, while most of the information in the report does not shed additional light on this case, I do note that Benny Wilson reported to the investigator that there were at least six other people in the store at the time of the incident. If Benny Wilson's statement to the investigator about the number of customers in BP is accurate, it is entirely possible that two minors may have tried to purchase covered tobacco products at the store around the same time. Respondent's assertion that a male customer attempted to purchase a covered tobacco product does not preclude the fact that Minor A, who is female, was able to purchase a covered tobacco product at approximately 6:06 PM on November 30, 2017. This would provide a reasonable explanation as to why Respondent's two witnesses testified that a male tried to purchase covered tobacco products, while the minor that was part of the investigation is actually female.<sup>3</sup> Thus, it is

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<sup>3</sup> On August 13, 2018, Respondent's counsel proffered a declaration where he stated that he drafted the documents signed by Respondent's witnesses and that "[t]he use of the male gender to refer to the CI is a default to the alternative 'he/she' or 'she'." Dkt. No.

not necessary that I discredit the testimony of Isaiah Wilson or Benny Wilson to find that Respondent violated the Act on November 30, 2017, as alleged.

It is also reasonable to infer that a store employee failed to check the minor's identification on November 30, 2017, in violation of 21 C.F.R. § 1140.14(b)(2)(i). It is undisputed that Minor A was 17 years old at the time of the inspection on November 30, 2017. Minor A reported to Inspector Laurin that Respondent's employee did not request to see her identification prior to purchasing the covered tobacco products on November 30, 2017.

The testimony of both Ms. Sternberg and Inspector Laurin, supported by corroborating evidence, is sufficient to establish that it is more likely than not that on November 30, 2017, Respondent unlawfully sold covered tobacco products to Minor A, in violation of 21 C.F.R. § 1140.14(b)(1), and failed to verify the photographic identification of Minor A, in violation of 21 C.F.R. § 1140.14(b)(2)(i). 21 C.F.R. § 17.33(b). Further, Respondent failed to establish any affirmative defense by a preponderance of the evidence. 21 C.F.R. § 17.33(c).

Accordingly, I find that the facts as outlined above establish Respondent's liability for five violations of the Act.

### **B. Civil Money Penalty**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent BP is liable for a CMP not to exceed the amounts listed in FDA's CMP regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the penalty amount of \$5,591 against Respondent for five violations of the Act and its implementing regulations within a 36-month period. Dkt. No. 1 ¶ 1. In its informal brief, CTP continued to assert that a \$5,591 CMP is appropriate. Dkt. No. 12, at 9-13.

Respondent's position is that the CMP is "too high," and should be reduced "due to Respondent's efforts at recruitment, training, and monitoring employees." Dkt. No. 3, at 3. In its informal brief, Respondent requests an opportunity to submit financial information on ability to pay if it is ordered to pay a CMP. Dkt. No. 14a, at 3. Section 3c of the March 13, 2018 Order directed the Respondent to submit all pre-hearing proposed exhibits by June 25, 2018. Dkt. No. 10. In an Order dated June 28, 2018, I reminded the parties of the deadline set forth in the March 13, 2018 Order. Dkt. No. 16. In an Order

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23. Counsel's declaration appears to refer to the typewritten statements of Isaiah and Benny Wilson dated August 6, 2018. In both statements, Isaiah and Benny Wilson refer to the minor as a "young man." Resp. Ex. 1 and 2. Accordingly, I find Respondent's declaration unpersuasive.

dated July 30, 2018, I extended the deadline to submit all supplemental prehearing exchange filings to August 6, 2018. Despite several opportunities to do so, to date, Respondent has not provided any financial information on its ability to pay.

I find that CTP met its burden by a preponderance of the evidence and concluded that Respondent committed five violations of the Act and its implementing regulations within a 36-month period. Accordingly, I now turn to whether a \$5,591 CMP is appropriate. When determining the amount of a CMP, 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 find that Respondent committed a total of five violations of selling tobacco products to minors, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the CMP amount should be set accordingly.

### **2. Respondent’s Ability to Pay and Effect on Ability to do Business**

Respondent has not argued that it does not have the ability to pay the \$5,591 CMP sought by CTP. Respondent has not presented any evidence that the penalty will affect the Respondent’s ability to continue to do business.

### **3. History of Prior Violations**

The current action is the second CMP action brought against Respondent since July 31, 2017, for violations of the Act and its implementing regulations. In the first CMP action, CRD Docket Number T-17-5541, FDA Docket Number FDA-2017-H-4505, Respondent twice violated the prohibition against selling covered tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(b), and 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)(2)(i). *See* CTP Ex. 1. Respondent settled the prior complaint with CTP for an undisclosed penalty amount on August 31, 2017. *See* CTP Ex. 2. Yet, three months later, on November 30, 2017, Respondent once again sold a covered tobacco product to a minor and failed to verify the identification of the purchaser. While Respondent has already paid a CMP for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

