

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-3860)

Complainant

v.

Hollistic, Inc.  
d/b/a 7-Eleven Store 25975A,

Respondent.

Docket No. T-17-764

Decision No. TB2744

Date: May 23, 2018

**INITIAL DECISION**

The Center for Tobacco Products (CTP) brings this action against Hollistic, Inc. d/b/a 7-Eleven Store 25975A (Respondent) for four violations of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 et seq., and its implementing regulations, 21 C.F.R. pt. 1140, within a twenty-four month period.

For the reasons discussed below, I find that Respondent violated the applicable regulations as alleged and, based upon Respondent's violations, I assess a civil money penalty of \$2,200.

**I. Procedural History**

CTP began this matter by serving an administrative complaint seeking a \$2,200 civil money penalty on Respondent at 4000 West Lake Mary Boulevard, Lake Mary, Florida 32746, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. On December 19, 2016, I issued an

Acknowledgment and Prehearing Order (APHO) that set various deadlines for the parties.

### **A. Discovery Disputes**

On January 26, 2017, CTP served a Request for Production of Documents to Respondent. In its request, CTP sought: documents regarding the ownership of Respondent's establishment; documents relating to employee penalties and/or discipline for failure to adhere to Respondent's policies or laws relating to the sale of tobacco products; and federal and state income tax returns to identify Respondent's income for 2016. On February 6, 2017, Respondent filed a Motion for Protective Order, asserting that those documents were not relevant.

On February 6, 2017, CTP received Respondent's Amended Request for Production of Documents, which sought, among other things, production of an unredacted copy of the photo identification used by the minor during the April 30, 2016 inspection. On February 28, 2017, CTP filed a Motion for a Protective Order, asserting that the documents sought by Respondent were privileged, undisclosed by law, and irrelevant.

CTP filed its opposition to Respondent's Motion for a Protective Order on February 28, 2017, and on March 10, 2017, Respondent filed its opposition to CTP's Motion for a Protective Order. After considering both motions and their respective responses, I issued an order granting in part and denying in part the parties' cross-motions for protective orders on April 6, 2017. That order:

- (1) required CTP to produce certain documents related to the alleged April 30, 2016 inspection;
- (2) required CTP to file a privilege log by April 28, 2017 regarding any documents it considered to be privileged and allowed time for Respondent to respond to that log;
- (3) denied Respondent's request for the unredacted identification used by the minor in the April 30, 2016 inspection alleged in CTP's complaint;
- (4) required Respondent to produce to CTP any responsive documents not subject to the Protective Order by April 28, 2017;
- (5) deferred Respondent's production of any documents relating to mitigation until later in these proceedings; and
- (6) extended the due dates for the parties' pre-hearing exchanges.

On April 28, 2017, CTP filed its privilege log identifying five entirely withheld documents and three documents released with redactions. Respondent filed a motion to compel disclosure of the documents set forth in the privilege log on May 15, 2017, arguing CTP improperly asserted the deliberative process and attorney-

client privileges as to certain documents related to CTP's inspection of Respondent. On May 30, 2017, CTP filed its response to Respondent's motion to compel.

On June 2, 2017, CTP filed a Motion to Compel Discovery and Extend Deadlines asserting Respondent had failed to produce any responsive documents by the deadline set forth in my April 6, 2017 Protective Order. Respondent filed its response on June 16, 2017, arguing it had already produced the documents requested by CTP. On June 19, 2017, CTP filed a Motion for Leave to File a Reply to Respondent's Opposition to Complainant's Motion to Compel Discovery. Without waiting for a ruling, CTP filed a reply to Respondent's response claiming Respondent had not provided sufficient documents in response to certain of its requests. On June 29, 2017, I denied CTP's Motion to Compel because it failed to articulate which specific responses were at issue, but permitted CTP to file an amended motion to compel.

CTP filed a Second Motion to Compel Discovery on July 13, 2017, asserting Respondent had failed to produce documents to several specific requests. Respondent filed a response on July 27, 2017. On September 8, 2017, I issued an order denying both Respondent's May 15, 2017 Motion to Compel and CTP's July 13, 2017 Motion to Compel.

### **B. Pre-hearing Conference and Hearing**

CTP filed its pre-hearing exchange on July 14, 2017, submitting its informal brief and fourteen exhibits, which included the declarations of two witnesses. Respondent filed its pre-hearing exchange on August 4, 2017, including its informal brief and eight exhibits,<sup>1</sup> which contained the declaration of one witness.

I held a pre-hearing conference by telephone with the parties on September 28, 2017. Both parties expressed the desire to proceed with a hearing in order to cross-examine each other's witnesses. CTP offered two witnesses for the hearing: Laurie Sternberg, who would testify that the tobacco products at issue in this case were sold in interstate commerce; and Jose Rodriguez, who conducted the inspection of Respondent's establishment on April 30, 2016, the date of the alleged violation. Respondent's counsel stipulated to Ms. Sternberg's testimony. For its part, Respondent offered one witness for cross-examination at the hearing: Mr. Paramjeet Singh, the principal of Hollistic, Inc.

I accordingly held a hearing by telephone on November 15, 2017. During the course of the hearing, I admitted the parties' exhibits and the uncontested

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<sup>1</sup> Respondent submitted one numbered exhibit and seven exhibits labeled A through G.

testimony of CTP witness Laurie Sternberg into evidence. Hearing Transcript (Tr.) at 8. CTP cross-examined Mr. Singh, *id.* at 9-10, while Respondent cross-examined Inspector Rodriguez. *Id.* at 12-16.

On November 17, 2017, I issued a post-hearing order notifying the parties that a transcript of the November 15, 2017 hearing would be prepared and that the parties would have 10 days from its filing to propose any corrections. My order also provided the parties until February 9, 2018 to file post-hearing briefs, stating:

Briefs shall not exceed 25 pages. While I have made no determination as to liability in this matter, the Respondent may at that time submit any evidence and arguments regarding mitigation of the monetary penalty. Should I find liability, Complainant shall be given an opportunity to respond to any evidence and arguments provided.

Nov. 17, 2017 Post-hearing Order at 1. The transcript was filed on December 5, 2017.<sup>2</sup> Both parties submitted their post-hearing briefs on February 9, 2018.

On March 22, 2018, I directed CTP to provide a response to Respondent's arguments for mitigation set forth in its post-hearing brief. CTP submitted its "Response to Mitigation Evidence and Argument in Respondent's February 9, 2018, Final Hearing Brief" (CTP Response) on April 9, 2018.

## **II. Applicable Law**

CTP seeks to impose a CMP against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found 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).

The government may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. *Id.* at § 331(f)(9). The implementing regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1).<sup>3</sup> The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. *Id.* at § 1140.14 (a)(2)(i).

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<sup>2</sup> Respondent proposed striking the name of one of its attorneys, Himanshu Patel, from page two of the transcript as he did not appear at the hearing. Rather than order correction of a minor error in the transcript, I instead note here for the record that Mr. Patel did not appear at the hearing.

<sup>3</sup> On August 8, 2016, the citations to certain tobacco violations changed. *See* <https://federalregister.gov/a/2016-10685>.

### III. Discussion

#### A. Respondent committed four violations of the Act within a 24-month period as alleged by CTP.

CTP alleges that Respondent twice violated the Act on April 30, 2016 by impermissibly selling cigarettes 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. Complaint ¶ 8.

CTP also asserted it had previously initiated a complaint against Respondent on January 19, 2016 for three additional violations that took place in February and September 2015. *Id.* at ¶ 10; CTP Ex. 2. The prior complaint alleged that Respondent had committed two violations on February 27, 2015 by selling cigarettes to minors and failing to verify their age, and another violation on September 25, 2015 by selling cigarettes to minors. *Id.*

Respondent settled the prior action by admitting the 2015 violations occurred. *Id.* at ¶ 11; CTP Ex. 3. Respondent also explicitly acknowledged that the violations to which it admitted could be counted in determining the total number of violations for future enforcement actions. *Id.* Because CTP customarily counts the first two violations as one, the current alleged violations, which Respondent denied in its Answer, amount to the third and fourth violations in a 24-month period.

CTP's case against Respondent relies on the direct testimony provided in a written declaration by Jose Rodriguez, an FDA-commissioned officer, as well as evidence submitted to corroborate his testimony. CTP Ex. 8. Mr. Rodriguez's duties include conducting "undercover buy" inspections to determine whether retail outlets are unlawfully selling tobacco products to minors. *Id.* at 1-2. During these inspections, Mr. Rodriguez provides direct oversight to state-contracted minors attempting to purchase tobacco products from retail establishments similar to the one operated by Respondent. *Id.* at 2. These minors were required to be 16 to 17 years old, possess valid state-issued identification, and undergo training to participate in the undercover buy inspections. *Id.*

Mr. Rodriguez testified that he went to Respondent's place of business on April 30, 2016 accompanied by a minor I identify as Minor A, in order to conduct a "follow-up compliance check inspection." CTP Ex. 8 at 2-3. Before the inspection, Mr. Rodriguez confirmed that Minor A was carrying photographic identification and did not have tobacco products in his possession. *Id.* at 3. Mr. Rodriguez testified that he entered the establishment shortly after Minor A and stood in an area of the store with an unobstructed view of the sales counter and

Minor A. From that vantage point, Mr. Rodriguez observed Minor A purchase a package of cigarettes from an employee of Respondent, who did not provide Minor A with a receipt after purchase. *Id.* Mr. Rodriguez also observed that Minor A did not present any identification prior to the purchase. *Id.*

After the purchase, Mr. Rodriguez and Minor A exited the store and returned to his vehicle, where Minor A immediately gave him the pack of cigarettes, which he observed to be a package of Newport Box cigarettes. CTP Ex. 8 at 3. Mr. Rodriguez labeled the cigarettes as evidence, and took photographs of the package. *Id.*; *see also* CTP Ex. 12. Mr. Rodriguez recorded the inspection shortly thereafter in the FDA's Tobacco Inspection Management System (TIMS).

Mr. Rodriguez's testimony, if taken to be true, proves Respondent unlawfully sold a tobacco product to a minor and failed to verify that minor's age. The corroborating evidence provided by CTP, consisting of photographs of the pack of cigarettes allegedly sold to Minor A and then transferred to Mr. Rodriguez's custody, is consistent with that testimony.

Respondent denies the events Mr. Rodriguez testified about took place on April 30, 2016, but has provided no direct evidence to refute his testimony. In its cross-examination of Mr. Rodriguez, Respondent focused on Mr. Rodriguez's recollection of the April 30, 2016 inspection, asking questions regarding the specific timeline of events from the inspection start to the filing of the TIMS report (Tr. at 21-24); whether Mr. Rodriguez physically inspected Minor A's wallet to determine if Minor A had any other form of identification (Tr. at 25); and whether Mr. Rodriguez maintained a constant or unobstructed view of the April 30, 2016 transaction at issue (Tr. at 28-29).

Respondent now contends that Mr. Rodriguez testimony should be considered suspect because he "could not even independently recall the inspection in question." Post-Hearing Brief of Respondent (Resp. Post-Hearing Brief) at 2. Respondent argues that Mr. Rodriguez's reliance on his April 30, 2016 narrative report during his cross-examination testimony demonstrates he was an unreliable witness. *Id.* at 2-4; 9-11. Respondent relies on *Center for Tobacco Products v. Chambers Drive, Inc. d/b/a Dynasty Deli Quick Shop*, ALJ Ruling No. 2012-3 (2012), to argue that CTP cannot carry its burden of proof on business records alone. Resp. Post-Hearing Brief at 12.

Respondent's reliance on that particular ruling is profoundly misplaced. A ruling by another Administrative Law Judge (ALJ) is not binding but merely persuasive, and only then if the facts suggest a similar analysis under the law would yield a similar outcome. But the circumstances of that case differed significantly. CTP filed a motion for summary disposition and as such, needed to demonstrate no

genuine issue of material fact existed for the ALJ to adjudicate. *See Chambers Drive, Inc. d/b/a Dynasty Deli Quick Shop* at 4, citing 21 C.F.R. § 17.17(b). Examining the case in the context of summary disposition, the ALJ noted the inspector's practices were "rife with the potential for errors," observing that the inspector did not take photographs of the establishments during the inspection and did not prepare his narrative report until later in the day after he had visited multiple establishments. *Id.* She also pointed out deficiencies in the narrative statement of the minor who performed the undercover buy, and ultimately concluded that CTP could not prevail on summary disposition, relying solely on documentary evidence, where the ALJ was required to draw all inferences in favor of the Respondent.

Here, however, CTP's investigating officer did indeed provide a declaration and appeared to testify, and I am not obliged to draw inferences in favor of Respondent. Nor am I required to consider the inspector's testimony in a vacuum, as Respondent would wish. Instead, I find Mr. Rodriguez' testimony well-supported by corroborating evidence, including the report he drafted on the date of the inspection at 12:56 p.m., a mere twelve minutes after the inspection at issue occurred. CTP Ex. 10. Mr. Rodriguez also contemporaneously documented the results of the inspection with five photographs of the purchased cigarettes timestamped at 12:52-12:54 p.m. on the date of the inspection. CTP Ex. 12. I note further that it is entirely customary to allow witnesses to refresh their recollection of past events using documents they prepared contemporaneously. I do not find Mr. Rodriguez' need to refresh his recollection years after the inspection at issue took place to undermine the veracity or integrity of his testimony.

Respondent submitted a signed declaration from Mr. Singh, Respondent's principal. Resp. Ex. 1. In his declaration, Mr. Singh offered no personal knowledge of the April 30, 2016 tobacco transaction, which Mr. Singh confirmed during cross-examination, stating he was not present at the establishment on April 30, 2016, at 12:44 p.m. Tr. at 9-10. Instead of offering any direct knowledge of the particular transaction in this case, Mr. Singh testified in his declaration that, in order to complete a tobacco transaction at his establishment, an employee would have had to either utilize a point-of-sale system that requires the clerk to manually enter a purchaser's date of birth or swipe the buyer's identification card. Resp. Ex. 1 at ¶ 21. Mr. Singh asserted his establishment maintained a "strict identification" policy for tobacco product sales and that employees were required to sign a copy of that policy. *Id.* at ¶ 24. Mr. Singh emphasized that Respondent's employees were required to complete a course regarding tobacco sales restrictions. *Id.* at ¶ 25. In sum, Mr. Singh stated:

I do not believe that the alleged sale on April 30, 2016 occurred as set forth in the CTP's evidence because in order for that to have happened, my employee would have needed to ignore its [sic] training and manually override the point of sale system. My employees know not to take such actions and in fact our compliance with age restricted product sales has been confirmed by [the] City of Lake Mary Police Department on multiple occasions.

*Id.* at ¶ 14.

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. *See* 21 C.F.R. § 17.33(b). As such, I must determine whether I am convinced the greater weight of the evidence supports Complainant's allegations. *See Sec'y of Labor v. Keystone Coal Min. Corp.*, 151 F.3d 1096, 1103 (D.C. Cir. 1998). In this case, taking into account all of the evidence submitted, I find the testimony of FDA inspector Jose Rodriguez to be credible and reliable, as it was well-corroborated by the additional evidence submitted by CTP, including his narrative report and the documented photographic evidence of the transaction.

By contrast, Mr. Singh's statement may be credible in the sense that he is not lying; but his belief that CTP's allegations are baseless because his employees must have conformed to his training is entirely speculative. But I need not consider his credibility because by his own admission, he was not present to observe the events at issue before me. I further note that Mr. Singh's claim to rigid compliance by his employees with age verification for tobacco sales is hardly consistent with Respondent's recent history of tobacco sales violations.

I, therefore, find that the weight of the evidence, including the testimony of Mr. Rodriguez, the underlying statement made by Minor A, and the corroborating physical evidence, establish Respondent's liability under the Act by a preponderance of the evidence.

#### **B. A Civil Money Penalty of \$2,200 is Warranted.**

Pursuant to 21 U.S.C. § 333(f)(9), Respondent is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its complaint, CTP sought to impose the maximum penalty amount, \$2,200, against Respondent for four violations of the Act and its implementing regulations within a 24-month period. Complaint at ¶ 1. CTP has maintained that this penalty is appropriate in both its Informal Brief and its post-hearing response addressing penalty factors. *See* Informal Brief of Complainant at 9-13; CTP Response.

Respondent argues that CTP's penalty is inappropriate, asserting that CTP should have used the penalty schedule in place in 2015, the time of its first violation, rather than the penalty schedule in place in 2016, the time of its most recent violation. *See* Resp. Post-Hearing Brief at 15.

CTP, however, argues that "the fact that the penalty amount is based on cumulative violations [does not mean] that subsequent penalties are locked into the amounts application at the time the initial violation occurred." CTP Response at 3. CTP notes that the "adjusted civil penalty amounts are applicable only to civil penalties assessed after August 1, 2016, whose associated violations occurred after November 2, 2015..." *Id.* citing 81 Fed. Reg. 61528 (Sept. 9, 2016).

CTP's argument is well taken, and Respondent has provided no legal basis for its position. Thus, I find Respondent's position to be without merit. In April 2016, the time of Respondent's most recent violation, \$2,200 was the maximum penalty amount applicable for four violations in 24 months. *Id.*

When determining the amount of a civil money penalty, 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. § 303(f)(5)(B).

### **1. Nature, Circumstances, Extent and Gravity of the Violations**

Within a 24-month period, Respondent committed three violations of selling cigarettes and/or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and two violations for failing to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette and/or smokeless tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2).

Respondent's repeated inability to comply with federal tobacco regulations as they relate to selling tobacco products to children is serious in nature. The civil money penalty amount should be set accordingly.

### **2. Respondent's Ability to Pay**

CTP is seeking a \$2,200 civil money penalty against Respondent. Respondent has not provided any argument or evidence that it lacks the ability to pay the \$2,200 civil money penalty.

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

Respondent claims that “a finding here of 21 C.F.R. 1140.14...may constitute” a breach of its franchise contract with 7-Eleven. Informal Brief of Respondent at 9; *see also* Resp. Ex. A. But even if an adverse finding may harm Respondent’s relationship with its franchisor, Respondent has not explained why a reduction in the penalty would therefore be appropriate. It would appear that harm to this relationship would occur no matter what penalty amount I imposed.

As Respondent has provided no arguments or evidence to suggest otherwise, I must conclude that imposition of a \$2,200 civil monetary penalty would not significantly affect Respondent’s ability to continue lawful retail operations.

### **4. History of Prior Violations**

As a result of random inspections, Respondent has now been caught selling tobacco products to minors three times, and twice failing to check their identification. The instant action before me is the second civil money penalty action that CTP has brought against Respondent. Respondent ultimately settled the first action brought against it by admitting all the allegations in CTP’s complaint, paying an agreed-upon penalty, and waiving its rights to contest those violations in a subsequent action. Complaint at ¶ 11. Despite the outcome of those proceedings, Respondent committed the exact same violations during an inspection only four months later, in April 2016. Application of this statutory factor militates towards imposition of a higher civil money penalty.

### **5. Degree of Culpability**

I have concluded that Respondent is liable for four violations as set forth in the Complaint. No evidence suggesting culpability by another party has been adduced. I hold Respondent fully culpable for each violation of the Act and its implementing regulations.

### **6. Additional Mitigating Factors**

In his declaration, Mr. Singh stated that Respondent, as required by 7-Eleven Inc. in its franchise agreement, is required to use a point-of-sale system to verify ages of tobacco customers at the time of purchase. Resp. Ex. 1 at ¶¶ 20-21. As he described it, the system used by Respondent required the sales clerk to manually enter a compliant birth date or swipe an identification card with a compliant birth date, in order to proceed with the sale. *Id.* at ¶ 21. Mr. Singh also testified that he posted signs around his store “regarding the requirement for patrons to show identification when purchasing...tobacco products” (*Id.* at ¶ 23); that he requires

Respondent's employees to sign a copy of the Respondent's policies on tobacco sales (*Id.* at ¶ 24); and that he requires all Respondent's employees to take a course regarding tobacco sales restrictions (*Id.* at ¶¶ 25-26). In addition to these measures, Mr. Singh stated that he voluntarily participated in an additional program, the Bars Program, in which 7-Eleven, acting as franchisor, would "send investigators to the store to conduct age restricted product sales." *Id.* at ¶ 30.

Respondent relies on previously established internal efforts at compliance in support of mitigation, but they do not appear to have been effective. It further appears that the prior penalty of \$250, for what Respondent's principal described as "seemingly minor violations," was insufficient to draw his attention to the importance of avoiding the real and substantial harm of selling tobacco to minors. *Id.* at ¶ 8. He now finds the penalty amount for the fourth violation to be of great "concern." *Id.* at ¶¶ 7-9.

I see no basis to mitigate the present penalty amount, given the lack of impression prior actions and penalties have made on Respondent. Presumably, the progressive penalty system utilized here will have its intended effect, and motivate Respondent to take meaningful action to comply with the Act and prevent the sale of tobacco products to children.

## 7. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$2,200 to be reasonable and appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9).

## ORDER

For the foregoing reasons, I enter judgment in the amount of \$2,200 against Respondent Hollistic, Inc. d/b/a 7-Eleven Store 25975A. 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.

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/s/  
Bill Thomas  
Administrative Law Judge