Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Deli-Icious Catering, Inc. d/b/a Convenient Food Mart
Docket No. A-17-50
Decision No. 2812
August 21, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Deli-Icious Catering, Inc. d/b/a Convenient Food Mart (Respondent) appeals the Initial Decision of an Administrative Law Judge imposing a $125 civil money penalty (CMP) against Respondent for committing three violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq*., and its implementing regulations, at 21 C.F.R. Part 1140, within a 24-month period. *Deli-Icious Catering, Inc. d/b/a Convenient Food Mart*, DAB TB757 (2017) (ALJ Decision). The Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) charged that on two occasions Respondent sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. CTP imposed a $500 CMP, which the ALJ reduced to $125 based on consideration of factors specified in the Act.

Respondent timely requested review of the ALJ Decision. For the reasons explained below, we find the ALJ Decision to be free of legal error and supported by substantial evidence. We therefore affirm the decision and sustain the CMP of $125.

Applicable Law

The Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq*., prohibits "the doing of any . . . act" with respect to a tobacco product "held for sale . . . after shipment in interstate commerce" that results in the product being "misbranded" and authorizes CMPs against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333(f)(9). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under the Act. 21 U.S.C. § 387c(a)(7)(B). The FDA may impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products . . . ." 21 U.S.C. § 333(f)(9). The Act directed the Secretary to establish the CTP within the FDA and authorized the Secretary to issue regulations restricting the sale and distribution of tobacco products. 21 U.S.C. §§ 387a(e), 387f(d).

The regulations, at 21 C.F.R. Part 1140, prohibit the sale of cigarettes or smokeless tobacco "to any person younger than 18 years of age" (i.e., a minor) and require retailers to "verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age" except that "[n]o such verification is required for any person over the age of 26[.]" 21 C.F.R. § 1140.14(a), (b)(1), (2) (2015).[1] Failure to comply with the applicable provisions of Part 1140 in the sale, distribution, and use of cigarettes and smokeless tobacco "renders the product misbranded" under the Act. 21 C.F.R. § 1140.1(b).

Regulations governing FDA CMP hearings, at 21 C.F.R. Part 17, during the time relevant to this appeal, specified the CMPs that FDA imposes for violations based on the number of violations and the period of time in which they are committed. For the time period relevant here, CTP assessed a CMP of $500, the maximum allowed for three violations within a 24-month period.[2] 21 U.S.C. § 333 note; 21 C.F.R. § 17.2 (2015) (table).[3]

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a "presiding officer" who is "an administrative law judge qualified under 5 U.S.C. 3105." 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiated this case before the ALJ by serving its Complaint on Respondent and filing it with the Civil Remedies Division of the Departmental Appeals Board (DAB). The regulations require a respondent to answer the complaint within 30 days or request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9.

Before the ALJ, the parties may request from each other production of documents "that are relevant to the issues before" the ALJ; a party must provide documents within 30 days of receipt of a request for production, and may file a motion for a protective order within 10 days of receipt of a request for production. 21 C.F.R. § 17.23(a), (d)(1). The ALJ may grant a motion for a protective order, in whole or in part, if he or she finds that the request for production is unduly costly or burdensome, will unduly delay the proceeding, or seeks privileged information. 21 C.F.R. § 17.23(d)(2).

---

[1] This decision uses the regulatory citations in effect at the time of the alleged sales to minors and the CTP complaint. These provisions are now at 21 C.F.R. § 1140.14(a)(1), (a)(2). 81 Fed. Reg. 28,974 29,103 (May 10, 2016).

[2] The Act and regulations set out two parallel CMP schedules, with lower CMPs assessed against a retailer who has an "approved training program." 21 U.S.C. § 333 note; 21 C.F.R. § 17.2 (2015). The FDA stated in CMP guidance that it would use the lower schedule for all retailers until it had developed regulations establishing standards for training programs. *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers – Responses to Frequently Asked Questions* at 13 (May 2015), http://www.fda.gov/downloads/TobaccoProducts/Labeling /RulesRegulationsGuidance/UCM447310.pdf.

[3] Effective September 9, 2016, after the time period relevant here, the FDA removed the table of maximum CMPs from 21 C.F.R. § 17.2 and cross-referenced a new consolidated table of maximum CMPs "associated with statutory provisions authorizing such penalties for all HHS Agencies" at 45 C.F.R. § 102.3. 81 Fed. Reg. 62,358 (Sept. 9, 2016); 81 Fed. Reg. 61,538, 61,565 (Sept. 6, 2016).

A respondent may appeal the ALJ's decision (which the regulations refer to as the "initial decision") to the Departmental Appeals Board (Board). 21 C.F.R. §§ 17.45, 17.47. The Board "may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion)," or "reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined" by the ALJ. 21 C.F.R. § 17.47(j).

Case Background[4]

CTP, by Complaint dated January 11, 2016, sought a $500 CMP against Respondent for three violations of the tobacco sales regulations within 24 months. CTP alleged in the complaint that on September 20 and October 4, 2015, "FDA-commissioned inspectors" had conducted inspections at Respondent's establishment located at 500 Station Street, Wilmerding, Pennsylvania, 15148, and doing business under the name Convenient Food Mart. CTP Complaint at 2-3. CTP alleged that on September 20, 2015, a CTP inspector documented that a minor was able to purchase cigarettes and that Respondent failed to verify the minor purchaser's age by means of photographic identification, in violation of 21 C.F.R. § 1140.14(a) and (b)(1), respectively. *Id*.; ALJ Decision at 4. CTP also stated in the Complaint that it had issued a Warning Letter to Convenient Food Mart on July 16, 2015 alleging that on June 18, 2015, Respondent had committed the violations of "[s]ale to a minor (21 C.F.R. § 1140.14(a))" and "[f]ailure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1))."[5] CTP Complaint at 3; ALJ Decision at 3-4. According to the Complaint, the Warning Letter had stated that failure to correct the violations could result in a CMP action or other regulatory action by FDA. CTP Complaint at 4.

Respondent timely answered the complaint and denied the violations, and the case was assigned to an ALJ. On July 6, 2016, the ALJ granted CTP's motion for a protective order shielding from discovery identifying information about the minors who purchased the cigarettes (name, date of birth, unredacted identification) that Respondent had sought. *Ruling on Request for Protective Order* (July 6, 2016). The ALJ held that the information Respondent sought was irrelevant, given CTP's representations that the minors would not be called as witnesses. *Id*. at 1-2.

[4] The factual information presented in this section is undisputed and is taken from the ALJ Decision and the administrative case record before the ALJ. It is not intended to serve as new findings or substitute for any findings in the ALJ Decision.

[5] While the CTP Complaint alleged that Respondent committed four separate violations of the CTP regulations, two each on June 18 and September 20, 2015, CTP imposed the CMP based on the commission of only three violations within a 24-month period because, CTP states, it "has adopted a policy of counting the [two] regulation violations cited in the first Warning Letter as a single violation." CTP Resp. at 2 n.1.

On September 2, 2016, the case was transferred to the ALJ who issued the ALJ Decision. Letter from DAB Civil Remedies Division (Sept. 2, 2016). The ALJ scheduled a hearing by telephone for November 3, 2016. CTP filed declarations under penalty of perjury from four witnesses and 45 proposed exhibits, including its four witness declarations. Respondent filed a three-page "Pleading" (R. Br.) with 15 pages of unmarked documents (R. Exs.) including signed statements from five of Respondent's employees denying having sold tobacco products to anyone who appeared to be under age 27 without checking identification. R. Exs. at 11-15 (unnumbered). Respondent also filed letters from the Pennsylvania Department of Health indicating that Respondent had not sold tobacco to youths under 18 years of age during four compliance checks in 2011, 2010, 2009 and 2007; and materials it apparently gives to its staff describing its tobacco sales policy; and a handwritten sign from its establishment stating the FDA has taken over tobacco enforcement and requires ID checks of all purchasers 27 years of age and younger. *Id*. at 1-10.

Prior to the hearing, Respondent moved to dismiss the CTP Complaint with prejudice on the ground that it had never been properly served with a warning letter because its legal name is Deli-Icious Catering, Inc. and it has never done business as Convenient Food Mart. The ALJ denied the motion to dismiss, stating,

> Respondent has admittedly received the pleadings in this matter, including the Warning Letter sent to Convenient Food Mart[at 500 Station Street Wilmerding, PA 15148], and previously responded to them without raising the issue of an incorrect business name. An answer was filed in this matter that did not dispute the business name or the pleadings' caption. Further, Respondent admitted in his discovery that the person who responded to the Warning Letter sent to Convenient Food Mart was the person in charge of Respondent's day to day operations.

Order Denying Respondent's Motion to Dismiss at 3 (Sept. 27, 2016); *see* CTP Ex. 17 (Warning Letter, July 16, 2015).

The ALJ convened the hearing by telephone on November 3, 2016. The two CTP inspectors who conducted the inspections on June 18 and September 20, 2015 appeared for cross-examination. During the hearing, CTP objected to the admission of the five signed statements that Respondent filed on the ground that they were not made under penalty of perjury as required by the regulations, and the ALJ ruled that the five statements would be stricken from the record. Transcript of Hearing (Tr.) at 8-9; ALJ Decision at 2.

The ALJ Decision

In finding that Respondent committed the violations CTP alleged in the Complaint, the ALJ relied on the declaration testimony of the two inspectors who conducted the investigations at Respondent's business on June 18 and September 20, 2015, Ms. Huffman and Ms. Police. Each inspector, the ALJ found, is "an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors" and whose "inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent." ALJ Decision at 3, 4, citing CTP Exs. 42 (Huffman decl.) at 1-2, and 43 (Police decl.) at 1-2.

Ms. Huffman, the ALJ found, testified that on June 18, 2015, she went to Respondent's business with a minor who, Ms. Huffman confirmed, was carrying his photographic identification and had no tobacco products in his possession. *Id*. at 3, citing CTP Ex. 42, at 2-3. Ms. Huffman further testified that the minor went directly to the sales counter and that she saw the minor purchase a package of cigarettes from an employee of Respondent without providing photographic identification to the employee, who did not provide the minor with a receipt after purchase. *Id*. at 3-4, citing CTP Ex. 42, at 2-3. After the purchase, Ms. Huffman and the minor left the store and returned to Ms. Huffman's vehicle, where the minor immediately gave her the pack of cigarettes – which she observed were Newport cigarettes – and she then labeled the cigarettes as evidence, took photographs of the package, and later recorded the inspection in the FDA's "Tobacco Inspection Management System." *Id*., citing CTP Ex. 42, at 3.

Ms. Police testified that on September 20, 2015, she went to Respondent's business with a minor who, Ms. Police confirmed, was carrying her photographic identification and had no tobacco products in her possession. *Id*. at 4, citing CTP Ex. 43, at 2-3. Ms. Police testified that the minor entered the establishment and went directly to the sales counter and stood a few feet away from Ms. Police, who could hear and see the minor purchase a package of cigarettes from an employee of Respondent without providing photographic identification to the employee, who did not provide the minor with a receipt after purchase. *Id*., citing CTP Ex. 43, at 2-3. After the purchase, Ms. Police and the minor left the store and returned to Ms. Police's vehicle, where the minor immediately gave her the pack of cigarettes – which she observed were Newport cigarettes – and she then labeled the cigarettes as evidence, took photographs of the package, and later recorded the inspection in the FDA's Tobacco Inspection Management System. *Id*., citing CTP Ex. 43, at 3.

The ALJ found that Ms. Huffman's and Ms. Police's testimony, along with "corroborating evidence consisting of photographs of the packs of cigarettes that were obtained from each minor on June 18, 2015 and September 20, 2015, are proof that Respondent unlawfully sold tobacco products to a minor, and failed to check the minor's identification before making the sales." *Id*. at 4-5.

The ALJ rejected Respondent's assertions "[t]hroughout the case . . . that the tobacco sales did not occur and that the name of the retail establishment was misrepresented" as well as Respondent's argument that CTP's evidence was hearsay. *Id*. at 5.

Regarding the name of Respondent's business where the inspections occurred, the ALJ noted that Respondent "has argued that its legal name is Deli-Icious Catering, Inc. and that any correspondence sent to Convenient Food Mart should be disregarded" and that it thus "is entitled to a new Warning Letter because the first one [dated July 16, 2015] was addressed to Convenient Food Mart." *Id*. at 5. The ALJ rejected this argument, finding "sufficient grounds to determine that Respondent received the Warning Letter sent to 'Convenient Food Mart' and that the Inspectors were not incorrect when they included the name in their reports." *Id*. Specifically, the ALJ found "ample testimony provided along with photographic evidence showing that Respondent's establishment has a sign on the building reflecting the name 'Convenient Food Mart'," and "further evidence that an employee of Respondent received the Warning Letter and sent a response back to CTP." *Id*., citing CTP Ex. 20 (Respondent's July 20, 2015 reply to warning letter); *see also* CTP Exs. 17-19 (July 16, 2015 warning letter addressed to 500 Station Street, Wilmerding, Pennsylvania, 15148 and UPS shipping and delivery confirmations). The ALJ thus found it "clear that whether or not Respondent does business under the name 'Convenient Food Mart', tobacco products were sold to minors at Respondent's establishment on June 18, 2015 and September 20, 2015" and that "an allegedly improperly addressed Warning Letter does not sever Respondent's liability for its employee's sale of tobacco products to a minor." ALJ Decision at 5.

Regarding Respondent's "request that CTP's evidence be stricken as hearsay," the ALJ noted that in an FDA tobacco hearing, the ALJ "determines the admissibility of evidence and has discretion to apply the Federal Rules of Evidence when deemed appropriate" but that "the Federal Rules of Evidence," which restrict the admission of hearsay evidence, "are not controlling in an administrative hearing." *Id*., citing 21 C.F.R. Part 17; *see* 21 C.F.R. § 17.39(a)-(c) ("presiding officer shall determine the admissibility of evidence [and] shall not be bound by the 'Federal Rules of Evidence[]'" and "shall exclude evidence that is not relevant or material"). The ALJ found that the two inspectors' testimony that they each "personally witnessed the tobacco sale and observed the minor enter Respondent's establishment without cigarettes and subsequently leave the store

with cigarettes in hand. . . . plus the corroborating evidence, leads to the inference that the minors could only have obtained cigarettes by purchasing them at Respondent's business establishment." ALJ Decision at 5-6.

The ALJ also denied Respondent's request to reconsider an order the ALJ issued during the hearing to strike Respondent's five witness statements. The ALJ struck the statements, as CMS requested, on the ground that they were not made under oath whereas the regulations require that written direct testimony "shall be admitted in the form of a written declaration submitted under penalty of perjury." *Id*. at 6, quoting 21 C.F.R. § 17.37(b). While noting that Respondent had later "resubmitted the statements with a declaration page purported to be signed by the witnesses" the ALJ found that "th[e]s[e] alleged declaration[s] [are] now well past the September 29, 2016 due date" the ALJ had set for filing witness statements and other evidence. *Id*. The ALJ also stated that "even if the statements are considered, I do not find that they are enough to overcome the testimony and corroborating evidence presented by CTP." *Id*.; *see Order Re Prehearing Conference* (Sept. 9, 2016); *Order Scheduling In-Person Telephone Hearing* (Sept. 20, 2016).

The ALJ also determined that a CMP of $125 was appropriate under the Act for three violations within a 24-month period, instead of the $500 CMP that CTP had imposed. The ALJ cited and discussed the factors that the Act requires be taken into account when determining the CMP: "the nature, circumstances, extent[,] and gravity of the [violation or] 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." ALJ Decision at 6, quoting 21 U.S.C. § 333(f)(5)(B).

Regarding "the nature, circumstances, extent[,] and gravity" of the violations, the ALJ noted that Respondent "committed two violations of selling tobacco products to minors, and two violations for failing to verify" that "the purchasers were 18 years of age or older" and concluded that "[t]he repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly." *Id*. at 7. The ALJ found that "Respondent has not presented any evidence that it does not have the ability to pay the $500" CMP that CTP sought. *Id*. Regarding Respondent's history of prior violations, the ALJ again noted that Respondent provided "evidence of inspections done by the State of Pennsylvania where tobacco products were not sold to minors." *Id*. The ALJ also found Respondent "fully culpable for all three violations" and, as "Additional Mitigating Factors," noted that Respondent "has also provided evidence that it has implemented new polices and no longer allows

judgment calls from its employees about when to card tobacco product purchasers" and "explains that its employees must now card everyone who is in their mid-thirties and under." *Id*. Based on these analyses, the ALJ found "a penalty amount of $125 to be appropriate" under the Act provisions.[6] *Id*. at 8.

Standard of Review

"The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous." 21 C.F.R. § 17.47(k).

Analysis

I. The ALJ's finding that Respondent sold cigarettes to a minor on two occasions is supported by substantial evidence on the whole record.

The ALJ found that Respondent sold cigarettes to a minor without checking photo identification on two occasions within 24 months based on Inspectors Huffman's and Police's testimony that they each witnessed a minor whom they accompanied to Respondent's business at 500 Station Street, Wilmerding, Pennsylvania, 15148, purchase cigarettes without being asked to provide photo identification, on June 18 and September 20, 2015, respectively. ALJ Decision at 3-5; *see also* CTP Exs. 42, at 3; 43, at 2-3 (inspectors' declarations describing the sales and also stating that they each entered the store to witness the sales and stood a few feet away from the minor where they could hear and visually observe the transactions). The inspectors' testimony is consistent with the "narrative reports" they each completed on the day of the inspections. CTP Exs. 14, 34. The inspectors' testimony is also consistent with the "inspection results" shown in printouts of the FDA "Tobacco Inspection Management System" (TIMS) that, each inspector testified, she recorded shortly after the inspection. CTP Exs. 13; 33.

The ALJ also relied on the photographs that each inspector took of the packs of cigarettes that they obtained from each minor on June 18, 2015 and September 20, 2015 after the inspections, finding this "corroborating evidence" and the inspectors' testimony to be "proof that Respondent unlawfully sold tobacco products to a minor, and failed to check the minor's identification before making the sales" on those dates. ALJ Decision at 3-5. The photographs in the record are consistent with the ALJ's findings. CTP Exs. 4-9, 24-32.

[6] CTP did not appeal, and Respondent on appeal did not dispute, the ALJ's determination to impose a CMP of $125 instead of the $500 CMP that CTP had imposed. Neither party disputed the ALJ's analysis supporting her determination that a CMP of $125 was appropriate. We thus affirm the amount of the CMP without further discussion.

We find that substantial evidence on the whole record supports the ALJ's finding that Respondent sold tobacco products to a minor on June 18 and September 20, 2015, and did not check the minor's identification.

II. Respondent's arguments show no basis to reverse or modify the ALJ Decision.

On appeal of the ALJ Decision, Respondent continues to argue, as below, that CTP cannot properly impose the CMP because it served the warning letter and other notices to Convenient Food Mart, which Respondent asserts is not the legal name of its business. Respondent also argues that the ALJ erred in finding the violations because CTP did not establish that Respondent's business sold cigarettes to minors or failed to check identification, and that the ALJ's rulings excluding the written statements of its clerks and its representative's efforts to testify during the hearing impeded Respondent's ability to prove its case. For the reasons below, we conclude that none of these arguments justifies reversing or modifying the ALJ Decision.

A. *The ALJ did not err in striking the written statements of Respondent's employees.*

Respondent argues it should not be liable for the violations of the regulations because his employees verified that they did not sell cigarettes to anyone who appeared to be under the age of 27 years without checking their IDs. *See* 21 C.F.R. § 1140.14(b)(2) (2015) ("No such verification [that purchaser is 18 or over, by means of photographic identification containing the bearer's date of birth] is required for any person over the age of 26;"). Respondent argues that:

> Respondent's position is that the accused clerks were acting within the training they received while following the provided guidelines from Tobacco Free Allegheny. We have not had issues in decades with many congratulatory letters of "job well done" over the years. Specifically stated, the clerks are trained to card anyone that "APPEARS TO THEM TO BE UNDER 27" and to not sell tobacco to anyone that appears to them to be under the age of 27. When questioned about the allegations, the clerks all stated they followed these rules of using their judgment. The Respondent (myself, which from here on out I will refer to myself first person to mean Respondent) never admitted nor denied tobacco products were sold to a customer that appeared to my clerks to be under the age of 27. All the clerks, in writing under the rules of perjury, testified to the same.

Notice of Appeal (NA) at 2 (unnumbered). Respondent argues that the ALJ prevented Respondent from making this case by striking the five clerks' written statements and by refusing to permit Respondent's representative and president, Mr. Setz, to testify during his cross examinations of the two investigators whom CTP presented as witnesses. *Id*. Respondent also asserts that the ALJ violated the hearing regulations at 21 C.F.R. § 17.25(c) "by striking my witnesses at the hearing as opposed to 5 days prior as required." *Id*. Respondent asserts that these clerks "are the very people being accused of not carding then selling tobacco to customers that appeared to them to be over 27, implicating bad judgment." *Id*.

The ALJ did not err in striking the written statements of Respondent's five clerks. The ALJ's determination to strike the five statements at the hearing because they were not made under penalty of perjury was consistent with the regulations, which state that "[d]irect testimony shall be admitted in the form of a written declaration submitted under penalty of perjury." 21 C.F.R. § 17.37(b). Similarly, the ALJ did not err in declining to accept the declaration page that Respondent submitted (to the CTP attorney) on December 22, 2016 on the ground that it was filed late. ALJ Decision at 6. The ALJ twice notified the parties, in prehearing orders issued on September 9 and 20, 2016, that the deadline for filing exhibits was September 29, 2016. Respondent had notice from the regulations of how to submit testimony, and notice from the ALJ's orders of the deadline to submit testimony. The regulation Respondent cites, 21 C.F.R. § 17.25(c), states that "[u]nless a party objects within 5 days prior to the hearing," the documents the parties exchanged "will be deemed to be authentic for the purpose of admissibility at the hearing." On its face, this rule specifically addresses only objections to the authenticity of a party's exhibits, not other objections.

In any event, even if section 17.25(c) applied here, striking the written statements did not prejudice Respondent as the ALJ also found that "even if the statements are considered, I do not find that they are enough to overcome the testimony and corroborating evidence presented by CTP." ALJ Decision at 6. The ALJ did not err in her assessment of the five written statements. The statements (and Respondent's claims in its pleading), on their face, do not allege compliance with the regulations governing tobacco sales in 21 C.F.R. Part 1140. Each states, "I deny that I have ever sold tobacco products to anyone that appeared to me to be under the age of 27 without carding them for proper Identification."[7] R. Exs. at 11-15 (unnumbered).

[7] Curiously, while the clerks' statements themselves deny selling to anyone who appeared to be under 27, Respondent states inconsistently that in those statements the clerks "never admitted nor *denied* tobacco products were sold to a customer that appeared to my clerks to be under the age of 27." NA at 2 (emphasis added).

These statements are notable for failing to assert either that the employees did not sell cigarettes to minors on the dates that the inspectors observed the two sales to minors, or that the employees verified, through photo ID, the age of all persons aged 26 years or younger who sought to purchase cigarettes, as required by the regulations at 21 C.F.R. § 1140(a), (b)(1), (2) (2015). Instead, the employees essentially concede that they limited their ID checks to purchasers who, in their judgment, ***appeared*** to be 26 years or younger.

The regulations, however, do not incorporate any "appearance" or "judgment" standard and instead require that retailers check photo IDs of ***all*** persons aged 26 and younger who seek to purchase cigarettes. When FDA first published the rule excepting persons over age 26 from the requirement to verify the age of cigarette purchasers by means of photo ID, it explicitly rejected an "appearance" standard and made clear that retailers must check the IDs of ***every*** purchaser age 26 years and younger, "regardless of his or her appearance." FDA explained in the preamble–

> One comment . . . contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; . . . . Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age.
>
> * * *
>
> The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person's age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person "looked" like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

61 Fed. Reg. 44,396, 44,439 (Aug. 28, 1996).

Thus, the employees' statements that they checked the IDs of tobacco purchasers based on appearance do not allege compliance with the regulations and do not undermine CTP's case. *See* ALJ Decision at 6 ("I do not find that they are enough to overcome the testimony and corroborating evidence").

Respondent's statements also indicate it employed an appearance or judgment standard in determining whether or not to request ID. Respondent in its Answer to the CTP Complaint acknowledged that it does not consistently check IDs, stating that "being in a small town market, if we know a customer personally or have carded them before, we do

not have to card again." Answer to CTP Complaint at 1. In its Post-Hearing Brief, Respondent similarly stated that it is "our employees[']written testimony that they did not sell tobacco to anyone that appeared to them to be under the age of 27." R. Post-Hearing Br. at 6 (unnumbered); *see also* NA at 2 ("the clerks are trained to card anyone that 'APPEARS TO THEM TO BE UNDER 27' and to not sell tobacco to anyone that appears to them to be under the age of 27" and "all stated they followed these rules of using their judgment").

Respondent also argues that its clerks were following state-issued guidelines, citing an undated, unlabeled brochure, which Respondent filed amid other materials from the Pennsylvania Department of Health, stating that "[r]etailers must implement a written policy against selling tobacco to minors which includes: . . . A requirement that an employee ask any person who appears under the age of 25 for a valid photo ID as proof of age prior to making a sale," on which the number '25' has been changed to '27' in hand writing. R. Exs. at 8 (unnumbered). That instruction, which conflicts with the plain language of the federal regulation, is not relevant in this proceeding, which concerns only compliance with federal, not state, requirements.

Thus, the ALJ did not err in striking the written statements Respondent submitted unsworn, contrary to the regulations, or in declining to admit those statements when Respondent submitted them with a declaration page after the hearing and beyond the deadline the ALJ set for the parties to file their exhibits.[8]

Respondent also argues that its president, Mr. Setz, who represented Respondent before the ALJ and on appeal, "was not permitted to testify to anything" at the hearing. NA at 2. This is a mischaracterization of the record. At the hearing, CTP objected that parts of Mr. Setz's cross-examination of the two FDA inspectors (in his capacity as Respondent's representative) was testimonial in nature, and the ALJ properly sustained those objections.[9] Tr. at 16-18, 25-26. The record reflects no proffer of testimony by Mr. Setz in the capacity of a witness either before or during the hearing, and the ALJ, thus, did not disallow any such testimony. Indeed, after one of CTP's objections to Mr. Setz's

[8] Even if we had concluded that the ALJ erred in striking the written statements, we would conclude that the error was harmless and thus not a basis for disturbing the ALJ's ruling since the content of those statements, for the reasons discussed above, do not help Respondent's case. *See* 21 C.F.R. § 17.48 ("The presiding officer and the entity deciding the appeal at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.")

[9] For example, Mr. Setz sought to state during cross-examination of CTP's witnesses, that at least at the time of the hearing, Respondent's employees did not match the FDA inspectors' descriptions (in their narrative reports) of the store clerks observed selling cigarettes to the minors on June 18 and September 20, 2015. Tr. at 18, 25. Aside from the fact that it was improper for Mr. Setz to attempt to testify during his cross-examination of CTP's witnesses, testimony as to the appearance of Respondent's employees as of the date of the hearing would not undermine the inspectors' contemporaneous reports of their observations at Respondent's establishment over a year earlier.

testifying while cross-examining CTP's witnesses, Mr. Setz stated that he "didn't realize [he] was testifying." Tr. at 26. We also note that although the ALJ offered to swear in Mr. Setz, along with the two inspectors, because CTP had reserved its right to call him as a witness (Tr. at 10), CTP did not call him as a witness.

B. *The ALJ did not rely on inadmissible hearsay testimony or err in refusing to permit discovery of personally identifying information about the minors who participated in the investigations.*

Respondent argues that the ALJ should not have relied on the inspectors' testimony because it was hearsay and unreliable, and disputes the ruling of the ALJ initially assigned to the case to grant a protective order shielding personally identifying information about the minors from discovery by Respondent. Respondent argues:

> The only witnesses of these allegations, that were supposedly present, provided scripted testimony of hearsay, observations, presumptions and false statements. Flaws in their testimony and not having a store receipt proving the tobacco came from Deli-Icious Catering Inc. do not meet the preponderance of evidence required to overcome innocent until proven guilty. All alleged minors have been struck from the case reducing further the ability to produce the preponderance of evidence.

NA at 2.

These arguments show no error in the ALJ Decision. First, the inspectors' testimony on which the ALJ relied was not hearsay because they testified to their personal observations. As the ALJ stated, the inspectors each testified that they "personally witnessed the tobacco sale and observed the minor enter Respondent's establishment without cigarettes and subsequently leave the store with cigarettes in hand." ALJ Decision at 5. The ALJ found this testimony, "plus the corroborating evidence" that the ALJ described as "photographs of the packs of cigarettes that were obtained from each minor" on June 18 and September 20, 2015 "leads to the inference that the minors could only have obtained the cigarettes by purchasing them at Respondent's business establishment." *Id*. at 4, 5-6.[10]

[10] While the ALJ cited the inspectors' testimony that they verified that the minors were carrying photo identification and had no cigarettes prior to entering the store, which could be viewed as hearsay, the ALJ did not rely on that testimony. ALJ Decision at 3-4. Additionally, hearsay is not inadmissible in these administrative proceedings. *See* 21 C.F.R. § 17.39(b) ("Except as provided in this part, the presiding officer shall not be bound by the 'Federal Rules of Evidence.' However, the presiding officer may apply the 'Federal Rules of Evidence' when appropriate, e.g., to exclude unreliable evidence."); *see also J. Peaceful, L.C. d/b/a Town Market*, DAB No. 2742, at 10 n.7 (2016) ("inspector's hearsay testimony in any event would not have been automatically inadmissible . . . as the Board has long observed, hearsay is admissible in administrative proceedings generally and can be probative on the issue of the truth of the matter asserted, where sufficient indicia of reliability are present").

Second, the prior ALJ did not err in refusing to order discovery of the minors' personally identifying information as irrelevant where CTP stated it would not, and did not, call them as witnesses. The Board has previously concluded that where CTP did not rely on testimony from minors, the Respondent merchant had not shown a need for personally identifying information about the minors, such as their unredacted state-issued identification, "that outweighs the potential harm [to the minors] of disclosure under these circumstances." *TOH, Inc. d/b/a Ridgeville Serv. Ctr.*, DAB No. 2668, at 7 (2015). The Board found that the ALJ's protective order limiting disclosure of the minors' identification licenses to redact personally identifying information to be "a reasonable exercise of his discretion," under 21 C.F.R. § 17.28(b). *Id*. at 7-10. That regulation, the Board noted, authorizes "'any order which justice requires to protect a party or person' from oppression, undue burden or expense, clearly unwarranted invasion of personal privacy, or 'other information that would be withheld from public disclosure'" and thus conferred "broad discretion" on the ALJ in granting protective orders. *Id*. at 10.

C. *The ALJ did not err in concluding that CTP's use of the allegedly incorrect name for Respondent's business "does not sever Respondent's liability for its employee's sale of tobacco products to a minor."*

Respondent as below continues to dispute "that Deli-Icious Catering Inc does business as Convenient Food Mart which is patently false" and argues by analogy that "in all fairness, you cannot serve a warning letter to K-Mart when it's technically for J.C. Penny and becomes considered legally served just because they are in the same plaza." NA at 2. Respondent, however, does not deny that its business location is at 500 Station Street, Wilmerding, Pennsylvania 15148, or that it received the FDA notices sent to that address including the Complaint, which Respondent timely answered. Respondent also does not question the evidence (photograph and testimony) that its business location has a sign reading "Convenient Food Mart," and conceded that a "Convenient Food Mart sign" is "on the side of the building" that houses Respondent's business. R. Br. at 1; *see* CTP Ex. 42, at 2 (inspector's testimony that a sign above the door of the business bore the name "Deli-Icious Chicken/Pizza" and that a sign above the parking lot on the side of the business bore the name "Convenient Food Mart"); CTP Ex. 3 (photograph). In the same pleading, moreover, Respondent admitted that "we did receive a warning letter sent to our business address of 500 Station Street, Wilmerding Pa., 15148." R. Br. at 1.

Respondent cites no authority for the notion that we may invalidate CTP's enforcement action simply because the name that appears on Respondent's place of business at the address where the Respondent does business and to which the enforcement notices were sent may not be its legal name. Respondent does not deny that it does business – including the sale of tobacco products – at the address that is the subject of this

enforcement action and admits receiving the CTP correspondence at that address. Respondent has not shown any failure of notice at any point during the appeal process. Accepting Respondent's argument could permit a retailer to avoid enforcement actions by simply posting a sign that identified its establishment by a name other than its technically legal name.

Conclusion

We conclude that the ALJ Decision is legally sound and its factual basis is supported by substantial evidence. We affirm the ALJ Decision and sustain the $125 penalty that the ALJ found appropriate and entered against Respondent.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member