

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Stowers Enterprises, Inc. d/b/a BP
Docket No. A-19-50
Decision No. 2969
September 23, 2019

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Stowers Enterprises, Inc. d/b/a BP (Respondent) appeals the December 31, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a \$5,591 civil money penalty (CMP) against Respondent for five violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, over a period of 36 months. *Stowers Enterprises, Inc. d/b/a BP*, DAB TB3389 (2018) (ALJ Decision). The ALJ issued her decision based on the written record regarding an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA). In the Complaint, CTP alleged that, during an FDA inspection on November 30, 2017, Respondent's staff sold a package of two cigars to a person younger than 18 years of age without verifying, by means of photographic identification (photo ID) containing a date of birth, that the purchaser was at least 18 years old. The Complaint also alleged that Respondent committed similar violations on October 25, 2016 and May 31, 2017. The ALJ concluded that the evidence supported the allegations in the Complaint and established a basis for the \$5,591 CMP.

On appeal, Respondent raises arguments mainly concerning the ALJ's evidentiary rulings admitting CTP's supplemental evidence (CTP Exhibits 15 and 16) revealing the gender of the undercover minor who participated in the inspection after earlier – during discovery – permitting CTP to redact certain information identifying the minor. Respondent also argues that the CMP should be reduced. For the reasons explained below, we reject the arguments and affirm the ALJ Decision.

Applicable Law

The Family Smoking Prevention and Tobacco Control Act (TCA) amended the Act and instructed the Secretary to promulgate regulations restricting the sale, distribution, access, and promotion of cigarettes and smokeless tobacco to protect children and adolescents. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (June 22, 2009). The Act, as amended, prohibits 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 the FDA to impose certain remedies against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333. A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under 21 U.S.C. § 387f(d). *Id.* § 387c(a)(7)(B). Congress authorized the Secretary of Health & Human Services (Secretary) to adopt regulations that impose “restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product” as appropriate to protect public health. *Id.* § 387f(d). Congress also directed the Secretary to establish CTP within the FDA to implement the tobacco products provisions of the Act. *Id.* § 387a(e).

The regulations adopted by the Secretary effective August 8, 2016 (81 Fed. Reg. 28,974 (May 10, 2016)), which were in effect when CTP initiated its complaint in this case based on the November 30, 2017 inspection, prohibit a retailer from selling a covered tobacco product to anyone under the age of 18. 21 C.F.R. § 1140.14(b)(1). The regulations also require a retailer to verify by means of photographic identification containing the bearer’s date of birth that no purchaser of the covered tobacco product is under 18 years of age, except that no such verification is required for any person over the age of 26. *Id.* § 1140.14(b)(2).

CTP may seek to 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 regulations set out a table of annually-adjusted CMP amounts that may be imposed for violations of the regulatory requirements, with CMPs increasing for successive violations within a given time period. 21 C.F.R. § 17.2 (adopting 45 C.F.R. § 102.3 (table)). In 2017, during the time period at issue here, the maximum CMP “in the case of a fifth tobacco product regulation violation within a 36-month period” was \$5,591. 45 C.F.R. § 102.3 (table).

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a “presiding officer” who is “an [ALJ] qualified under 5 U.S.C. 3105.” 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before the ALJ by serving a complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The retailer (the respondent in the administrative appeal proceedings) requests a hearing by filing an answer to the complaint within 30 days but may request one 30-day extension. *Id.* § 17.9(a), (c). Assuming respondent files a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

A respondent dissatisfied with an ALJ decision may appeal that decision (to which the regulations refer as the “initial decision”) to the DAB. *Id.* §§ 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. *Id.* § 17.47(j).

Case Background¹

1. The Complaint and ALJ Proceedings

On December 19, 2017, CTP served a Complaint on Respondent seeking to impose a \$5,591 CMP for five violations of the Act and its implementing regulations within a thirty-six month period. ALJ Decision at 1-2, 4; Complaint ¶ 1. The Complaint alleged that on November 30, 2017, an FDA-commissioned inspector inspected Respondent's retail establishment and found two violations: 1) selling tobacco products to a minor in violation of 21 C.F.R. § 1140.14(b)(1); and 2) failing to verify that the purchaser was 18 years of age or older by means of photo ID bearing a date of birth in violation of 21 C.F.R. § 1140.14(b)(2)(i). Complaint ¶ 9. The Complaint specifically alleged that, during the inspection, "a person younger than 18 years of age was able to purchase a package of two Swisher Sweets cigars . . . at approximately 6:06 PM" and that "the minor's identification was not verified" before that sale. *Id.* The Complaint also set out a history of prior similar violations found on inspections on October 25, 2016 and May 31, 2017, and asserted that Respondent previously admitted to those violations.² *Id.* ¶¶ 11-12; ALJ Decision at 4. The ALJ noted that Respondent had "expressly waived its right to contest" the earlier violations in future CTP actions. ALJ Decision at 4; Complaint ¶ 12.

After timely answering the Complaint (ALJ Decision at 2), Respondent served on CTP a "Discovery Demand," seeking "case-related" evidence, including "the names and contact information of any witnesses involved in the investigation[.]" In response, CTP filed a motion for a protective order and, subsequently, a memorandum in support of the motion, asserting, *inter alia*, that CTP should not be ordered to produce documents that are privileged, irrelevant, or otherwise exempt from disclosure. Asserting that the only relevant characteristic of the undercover minor who participated in the inspection is his or her age, CTP sought to protect from disclosure the unredacted, state-issued photo ID of the minor and to produce narrative reports of the minor and the inspector with information identifying the minor other than his or her age redacted. CTP's Privilege Log and supporting memorandum at 7. CTP argued that the documents revealing the minor's identity reasonably could interfere with law enforcement proceedings, risk circumvention of the law, constitute an unwarranted invasion of the minor's privacy, and could endanger the minor's life and physical safety. Supporting memorandum at 8-13 (citing 21 C.F.R. § 20.64(a)(1), (3), (5) and (6)).

¹ The factual findings stated here are taken from the ALJ Decision and the administrative record. We make no new findings of fact, and the facts stated are undisputed unless we indicate otherwise.

² CTP counted the October 25, 2016 violations as one violation and the May 31, 2017 violations as separate individual violations (ALJ Decision at 4 & 4 n.1), resulting in three violations as of May 31, 2017. The Complaint filed after the November 30, 2017 inspection, alleging two additional violations, brought the total number of violations to five.

On March 13, 2018, the ALJ issued a Discovery Order in which she granted CTP a “limited protective order.” The ALJ wrote, in part:

I am satisfied that there could be substantial prejudice to CTP’s investigative process if I compelled it to turn over identifying information relating to [the undercover minor]. CTP has shown to my satisfaction that forcing it to turn over identifying information creates a risk of intimidating future potential minor witnesses from participating in CTP’s investigations. In *TOH, Inc. d/b/a Ridgeville Service Center*, Docket No. A-15-103, the Departmental Appeals Board (“Board”) held that an Administrative Law Judge did not err in withholding the unredacted identification of a minor because CTP did not rely on the minor to testify and the potential damage to the minor’s privacy and to CTP’s enforcement program justified the redaction. The Board wrote that “. . . [i]t does not follow, however, that the names or identities of the individual minor purchasers are essential to proving that these transactions occurred as alleged.” *Id.*

I will grant CTP a limited protective order. CTP is not required to produce unredacted copies of documents responsive to the requests. 21 C.F.R. § 20.64(a).

Discovery Order at 5. The ALJ determined she need not address CTP’s arguments concerning unwarranted invasion of the minor’s privacy and endangerment to his or her life or physical safety. *Id.* at 6.

Also on March 13, 2018, the ALJ issued an Acknowledgment and Pre-hearing Order establishing procedural deadlines for the case. ALJ Decision at 2. Each party submitted a pre-hearing brief, identified its proposed witnesses and exhibits, and offered numbered exhibits pursuant to that order. CTP’s exhibits included the written direct testimony of Inspector Laurin (CTP Ex. 4), who conducted the inspection on November 30, 2017. Respondent’s exhibits included the written direct testimony of two employees, B.W. and I.W., who attested that they were on duty at Respondent’s retail establishment on November 30, 2017 around the time the inspection occurred (Resp. Exs. 1 and 2),³ and the August 5, 2018 sworn declaration and undated report of a private investigator (retained by Respondent) who interviewed the two employees on February 15, 2018 (Resp. Ex. 3).

³ For each of the two employees, Respondent submitted a typed, one-page sworn declaration signed by the employee on August 6, 2018 and a brief handwritten (but not sworn) statement of the employee, signed December 27, 2017. The declarations were executed some eight months after the inspection; the handwritten statements were signed about a month after the inspection.

In its pre-hearing brief, Respondent noted that Inspector Laurin did not go into the establishment with the undercover minor and instead waited outside. On that basis, Respondent asserted that Inspector Laurin did not personally witness the minor purchase tobacco. Resp. Pre-Hearing Br. at 2 (citing CTP Ex. 4, at 3). Relying in part on its private investigator's report, Respondent presented a different narrative of what allegedly occurred. *Id.* at 2-3; ALJ Decision at 6 (stating that Respondent presented "a different scenario"). Respondent asserted that, at the time of the inspection, a minor male attempted to buy a "blunt" cigar, but was denied by the cashier, I.W., for lack of a photo ID. Resp. Pre-Hearing Br. at 2; ALJ Decision at 6. Respondent further asserted that the minor began "cussing," walked to the back of the store, and asked an "older man" to buy him a cigar. The "older man" then allegedly bought a cigar for that minor and exited the store. Resp. Pre-Hearing Br. at 2; ALJ Decision at 6. As further support for its narrative, Respondent offered the statement of B.W., who wrote (by hand) that, between 6:00 – 6:15 PM on November 30, 2017, a "young man" attempted to buy tobacco but was denied by the cashier (I.W.), went to the back of the store by the coolers, asked a man who was near the cooler area to buy the tobacco for him, and the man "bought the blunt for him." Resp. Ex. 1, at 2. B.W. attested that "[t]he cashier [I.W.] did not sell the tobacco product to the young man about 6-6:15 pm on Nov. 30, 2017, as he did not show ID, as I witnessed the event." *Id.* at 1. I.W. likewise wrote (by hand) that the young man went to the back of the store when he, I.W., did not sell the tobacco to him. Resp. Ex. 2, at 2. I.W. attested that he did not sell the tobacco to the young man. *Id.* at 1.

The ALJ held a telephone pre-hearing conference on August 8, 2018, during which each party indicated that it did not wish to cross-examine the opposing party's witnesses and agreed to a decision based on the written record. ALJ Decision at 2. The next day, the ALJ issued an order granting the parties time to submit any additional evidence, noting that "[b]oth parties indicated that they may submit additional evidence." August 9, 2018 Order at 1. The ALJ also established a deadline of August 23, 2018 for objections to any exhibits previously offered and any new, supplemental exhibits. *Id.*

On August 13, 2018, CTP filed a supplemental declaration of Inspector Laurin in which he attested that the undercover minor who participated in the inspection is female (CTP Ex. 15) and a redacted copy of that minor's probationary driver's license, with the minor's "sex" "F" revealed (CTP Ex. 16). Inspector Laurin testified that CTP exhibit 16 was "a true and accurate redacted copy" of the undercover minor's license. CTP Ex. 15, at 1. Respondent did not object to either exhibit. ALJ Decision at 3. Respondent's attorney also filed a declaration on August 13, 2018, attesting that he "drafted the documents signed by Respondent's witnesses" and that "[t]he use of the male gender to refer to the [minor] is a default to the alternative 'he/she' or 'she.'"

On October 5, 2018, Respondent filed a final brief reiterating that its two employees declared that a young male solicited a man in the store to purchase the tobacco for him. Resp. Final Brief at 1. Respondent stated, "[t]he gender of the [minor] should not be

used as a factor in consideration of credibility. The Complainant moved to conceal the identity of the [minor], including gender, appearance, skin color, height, hair, eye-color, etc., only to release the gender with the expectation to use that as a credibility challenge. The Complainant could have cross-examined the store employees but chose not to do so.” *Id.* Thus, Respondent argued, “[t]here should be no greater weight to the one eyewitness of Complainant over the two of the Respondent.” *Id.*

2. The ALJ Decision

The ALJ determined that Respondent violated 21 C.F.R. § 1140.14(b)(1) and (b)(2)(i) on November 30, 2017, and that CTP showed by a preponderance of the evidence that Respondent committed five violations of the Act and its implementing regulations within a 36-month period. ALJ Decision at 1, 4, 4 n.1, 9.

The ALJ noted that Respondent’s employees and the private investigator’s report repeatedly referred to the purchaser as a male, whereas CTP’s evidence, including the undercover minor’s (redacted) state-issued identification and Inspector Laurin’s testimony, indicated that the undercover minor purchaser is female and was 17 years old on the inspection date. *Id.* at 6, 7, 8. The ALJ found Inspector Laurin’s testimony – which “establishe[d] that [the undercover minor] did not have covered tobacco products in her possession before entering the store and had covered tobacco products upon leaving the establishment” and from which the ALJ inferred that the minor bought the cigars in the establishment – credible, comprehensive, “corroborated by photographic proof” that Respondent sold cigars to a minor on November 30, 2017, and not “discredit[ed]” by the employees’ testimony. *Id.* at 6, 7.⁴ The ALJ moreover noted that the minor’s statement to Inspector Laurin “confirms” that the minor was able to buy a package of Swisher Sweets cigars from an employee of Respondent’s establishment. *Id.* at 7. The ALJ also found it reasonable to infer that a store employee failed to check the minor’s identification before the sale since it was undisputed that the minor was only 17 years old at the time, and the minor reported that the clerk did not ask her for identification. *Id.* at 8.

The ALJ also explained how she weighed the evidence and why she found Respondent’s evidence less credible, reliable and persuasive. The ALJ noted in particular that the employees’ handwritten statements “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.” ALJ Decision at 6; *id.* at 7-8 n.3 (noting that the employees’ August 6, 2018 declarations were drafted by the Respondent’s attorney as evident based on the attorney’s own declaration, which the ALJ found “unpersuasive”).

⁴ The ALJ noted that, 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.” ALJ Decision at 6 n.2.

With respect to the private investigator's report, the ALJ stated that it was "more comprehensive" as compared to the employees' statements (*id.*), but nevertheless assigned it "little weight" since the investigator compiled the information discussed in the report and prepared the report "on or after February 15, 2018" about events that occurred on November 30, 2017 and "likely . . . in anticipation of a hearing" to follow as a result of CTP's initiation of a complaint on December 20, 2017. *Id.* at 7. The information in the report, the ALJ also noted, was "primarily hearsay."⁵ *Id.* In light of these considerations, the ALJ determined the December 27, 2017 handwritten statements of the employees to be their "most reliable account" of the event, and that they were more reliable as compared to the private investigator's second-hand reporting of the incident long after the fact. *Id.*

Moreover, while the ALJ found that "most" of the private investigator's report "does not shed additional light," she noted that B.W. reported to the private investigator that there were at least six other people in the store at the time of the alleged purchase (Resp. Ex. 3, at 2), which, if accurate, raised the possibility that two minors tried to buy tobacco at around the same time. ALJ Decision at 7. The ALJ stated, however, "Respondent's assertion that a male customer attempted to purchase a covered tobacco product does not preclude the fact that [the undercover minor], who is female, was able to purchase a covered tobacco product at approximately 6:06 PM on November 30, 2017." *Id.* This, the ALJ stated, could reasonably explain why the employees testified that a male tried to buy tobacco, while the undercover minor is female. *Id.* Thus, the ALJ concluded, she did not need to "discredit the testimony" of the employees "to find that Respondent violated the Act on November 30, 2017, as alleged." *Id.* at 7-8.

Having found Respondent liable for the violations, the ALJ determined that the penalty of \$5,591 is "reasonable and appropriate" under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9), and that the record contained no evidence of mitigating factors on which she could determine whether a reduction of the penalty amount would be appropriate. *Id.* at 8-10.

Standard of review

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

⁵ Hearsay is inadmissible under the Federal Rules of Evidence (which apply in federal courts, not in administrative proceedings such as those before the ALJ and the Board) unless an exception applies. *See generally* hearsay rules, Rules 801-807 of the Federal Rules of Evidence. An ALJ is not bound by the Federal Rules of Evidence, but may apply them if he or she determines it is appropriate to do so. 21 C.F.R. § 17.39(b). The ALJ evidently decided to admit the private investigator's report despite its hearsay content, but assigned less weight to the report, which was well within her broad discretionary authority over evidentiary matters under Part 17.

The Board reviews an ALJ's determination to admit evidence for abuse of discretion. *See Monroe Mobil, Inc. d/b/a BP*, DAB No. 2918, at 6-8 (2018) (stating that the regulations in 21 C.F.R. Part 17 "afford an ALJ considerable discretionary authority over the admission or exclusion of evidence" and finding no abuse of discretion or error by the ALJ in admitting redacted identification of the undercover minor who participated in an inspection).

Analysis

Respondent "raises two issues on appeal," which it states as follows:

- (1) Did the ALJ violate her own DISCOVERY ORDER, dated March 13, 2018, in granting submission in the record of CTP Exs. 15, 16 referenced on p. 7 of the DECISION? [and]
- (2) Did the ALJ commit error in stating on p. 10 of the DECISION . . . "Respondent failed to provide any evidence of the remedial measures taken or evidence to show when Respondent took such measures.

Notice of Appeal of Initial Decision and Brief (NA) at 1-2. With respect to the first issue, Respondent challenges the ALJ's ruling admitting CTP's Exhibits 15 and 16, which identified the gender of the minor purchasing the tobacco product, after the ALJ had previously granted CTP's protective order for this and other information identifying the minor. With respect to the second issue, Respondent challenges the ALJ's finding, for purposes of determining whether the CMP amount was appropriate, that Respondent did not provide evidence to support its claim that it had taken remedial measures that should be considered mitigating.

As we explain below, we conclude that the ALJ did not err or abuse her discretion in her ruling admitting CTP Exhibits 15 and 16; nor did she err in stating that Respondent had not submitted evidence to support its claim of mitigation. While Respondent effectively challenges the ALJ's consideration of the gender identification evidence by challenging her admission of that evidence in CTP Exhibits 15 and 16, Petitioner does not otherwise dispute that substantial evidence and the law support the ALJ's determination that CTP had a basis for imposing a CMP based on her finding that Respondent sold cigars to a minor and failed to verify the purchaser's age by photo identification on November 30, 2017, which, together with prior violations, established five violations within a 36-month period. Similarly, while Respondent disputes the ALJ's statement that Respondent did not present evidence to support its claim of mitigation, Respondent does not otherwise dispute that the ALJ lawfully imposed a \$5,591 penalty.

I. *The ALJ did not err or abuse her discretion in admitting CTP Exhibits 15 and 16 after declining to order CTP to produce the identifying information in those exhibits in discovery.*

Respondent takes issue with the ALJ's admitting into the record CTP exhibits 15 and 16 (Inspector Laurin's supplemental declaration; undercover minor's photo ID, redacted, except for the minor's gender). Respondent argues that the ALJ's admitting these exhibits was inconsistent with, or a departure from, her earlier, March 13, 2018 Discovery Order (limited protective order) in which the ALJ determined that CTP was not required to disclose such information. NA at 6-7. Respondent asserts that since the Discovery Order "was the law of the case" and the ALJ did not later "overturn or modify" that Order, *id.*, the ALJ should not have permitted CTP to proffer evidence revealing the undercover minor's gender as female after denying Respondent's request for information identifying the minor. *Id.* at 5. Respondent also argues that the ALJ's admission of the new exhibits violated the Federal Rules of Civil Procedure (Federal Rules) because they were submitted after the deadline imposed in the ALJ's pre-hearing order and, moreover, the ALJ "did not apply the analysis to allow additional evidence consistent with" the Federal Rules. *Id.* at 7. Thus, Respondent asserts, "the hearing process lacked due process, and was unfair." *Id.* Respondent requests that the Board either "remand for the release of the requested" portions of the minor's photo ID, or dismiss "the case either in the interest of justice or to protect CTP operations." *Id.* at 8.

We reject Respondent's arguments. The inconsistency Respondent alleges does not exist. Deciding whether CTP can be required to disclose identifying information in response to a discovery request, on the one hand, and deciding to admit an exhibit volunteering that information are entirely different matters. The ALJ's protective order was based on her conclusion, which – as Respondent does not dispute – was correct, as a matter of law, that CTP had established a basis for not disclosing the minor's identifying information (beyond age) in discovery and that the ALJ, therefore, would not mandate disclosure. That ruling did not preclude the ALJ's subsequent ruling permitting CTP to voluntarily produce some of the previously protected identifying information, especially since the handwritten and sworn statements of Respondent's employees were already in the record as Respondent's exhibits and by referring to the minor as a male seemed to be raising an issue of gender. *See* ALJ Decision at 2, 6. In addition, while Respondent now argues that the redacted portions of the undercover minor's photo ID should have been disclosed in discovery, Respondent did not object to CTP's motion for a protective order or state a basis for why the redacted information should have been disclosed even though the ALJ gave Respondent an opportunity to respond to CTP's motion. ALJ Decision at 2, 3; February 6, 2018 Order at 1 (citing 21 C.F.R. § 17.32(c)). In the absence of any objection to CTP's motion, on March 13, 2018, the ALJ granted CTP's motion. ALJ Decision at 2; Discovery Order at 2. Moreover, in its pre-hearing and final briefs, Respondent did not raise any argument concerning the ALJ's issuance of the protective order or state why it believed the evidence identifying the minor (redacted information)

was material to its defense. Resp. Pre-Hearing Br.; Resp. Final Brief. Accordingly, Respondent did not meet its burden under 21 C.F.R. § 17.23(d)(4) to show that the unredacted photo ID should have been produced. *See Chit-Chat Inc. d/b/a Scuttlebutts*, DAB No. 2936, at 9 (2019) (holding that the respondent did not satisfy its burden to show that requested documents should be produced because it did not timely respond to CTP's motion for a protective order).

As we read Respondent's statement of the "two issues" it raises (quoted above), Respondent's main concern with the ALJ's rulings is not that she declined to order production during discovery of the identifying information contained in CTP Exhibits 15 and 16 but, rather, that the ALJ subsequently admitted those exhibits and the gender information in them, identifying the minor purchasing the tobacco product as female. Respondent's apparent concern (or at least suggestion) is that the gender information adversely affected the ALJ's determination of the credibility of the handwritten statements and declarations (one sworn and one unsworn) it submitted from two of its employees identifying the purchaser as a male and caused the ALJ to decide in CTP's favor.

Respondent's concern is unfounded. The ALJ expressly stated, "[I]t is not necessary that I discredit the testimony of [the employees] to find that Respondent violated the Act on November 30, 2017 as alleged." ALJ Decision at 7-8. The ALJ found this unnecessary because of employee B.W.'s statement, to the private investigator Respondent had hired to investigate the incident, that there were at least six other people in the store at the time of the incident. *Id.* at 7; Resp. Ex. 3, at 2. The ALJ concluded that the presence of so many people at that time made it unnecessary to discredit the employees' testimony because the presence of these people "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 [CTP] investigation is actually female." ALJ Decision at 7. However, the ALJ made it clear that while she found it unnecessary to discredit the testimony of Respondent's employees, she also found that their testimony did not discredit or outweigh the testimony of the CTP inspector on which she relied – along with other evidence documenting the inspection and the written direct testimony of another CTP witness – in finding the sale of tobacco products to a minor had occurred as stated in the inspector's report and CTP's complaint. The ALJ stated,

Despite Respondent's arguments, I do not find the testimony of [the employees] to discredit the testimony of Inspector Laurin [who] testified credibly and comprehensively about his observations during the November 30, 2017, inspection. [footnote omitted] I also find Inspector Laurin's testimony is corroborated by photographic proof that Respondent sold a

package of Swisher Sweets cigars^[6] to Minor A on November 30, 2017, 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.

Id. at 6-7.⁷ Thus, the gender dispute is ultimately immaterial because the ALJ based her decision on the credibility and weight she afforded CTP's evidence regarding the minor's purchase of the tobacco product regardless of the minor's gender.

The Board defers to an ALJ's credibility determinations and weighing of the evidence unless there is a compelling reason for not doing so. *TOH, Inc., d/b/a Ridgeville Service Ctr.*, DAB No. 2668, at 18 (2015). We find no reason not to defer to the ALJ's credibility determinations and weighing of the evidence here, which we find well-explained and thorough.

Even if the ALJ's decision ultimately rested on CTP Exhibits 15 and 16, which it does not, we would find no basis for Respondent's objections now to their admission. Respondent did not raise any objection to the admission of CTP Exhibits 15 and 16 at the time CTP submitted them even though it had an opportunity to do so. ALJ Decision at 3. On August 9, 2018, the ALJ issued an order giving the parties an opportunity to submit any additional evidence, apparently in part because the parties themselves had indicated during the pre-hearing conference that they might wish to do so, and an opportunity to object to the admission of any new or previously offered exhibits. August 9, 2018 Order at 1, 2. Respondent availed itself of the opportunity to submit additional evidence when it offered the declaration of its attorney but remained silent when CTP offered exhibits 15 and 16. In the absence of any objection to either CTP exhibit by the established due date,

⁶ We note that I.W. (cashier) stated only that a young male attempted to buy a tobacco item. I.W. did not specifically identify the tobacco product. Nor did B.W. B.W. stated only that I.W. refused to sell a "blunt" to the young male. *See* ALJ Decision at 6; Resp. Exs. 1, at 2 and 2, at 2.

⁷ The ALJ also gave "little weight" to the report of the private investigator hired by Respondent because the investigator prepared that report several months after the incident and "most likely . . . in part in anticipation of a hearing in this matter." She also found the private investigator's report "primarily hearsay." ALJ Decision at 7.

the ALJ admitted both into the record by order issued August 28, 2018.⁸ We see no reason not to accept the ALJ's determination to admit those exhibits as a reasonable exercise of her discretionary authority over evidentiary matters under 21 C.F.R. Part 17.⁹ *See Monroe Mobil*, DAB No. 2918, at 6; 21 C.F.R. § 17.39(a)-(e), (f). The ALJ apparently found CTP exhibits 15 and 16 revealing the gender of the undercover minor relevant (though ultimately not material) in light of Respondent's challenge to the credibility of a potential CTP witness (undercover minor) and admitted them for this reason, *see* ALJ Decision at 7, an action well within the bounds of the ALJ's authority.

To the extent Respondent is challenging the ALJ's having declined to order CTP to produce the identifying information in discovery, that challenge is unwarranted. The regulations in 21 C.F.R. Part 17 "empower the ALJ to balance the need for parties to obtain documents that are relevant to the issues before [her] with crafting a protective order where a party's request is too costly or burdensome, will cause too much delay, or seeks privileged information." *TOH, Inc.*, DAB No. 2668, at 10 (citing 21 C.F.R. § 17.23(a) and (d)(2)). The ALJ issued a limited protective order to balance the serious, legitimate concerns regarding the adverse impact that releasing information about the undercover minor could have on the integrity of CTP's enforcement program against the need for evidence relevant to determining whether a violation occurred. Discovery Order at 5. As to the latter, the ALJ noted, in particular, that, in *TOH*, the Board found no ALJ error in permitting CTP to withhold information concerning the undercover minor's identity because CTP in *TOH* did not rely on the minor to testify, among other reasons, and recognized that the names and identities of the individual minor purchasers may not be essential to prove that the transactions occurred as alleged. *Id.* The ALJ in her exercise of discretion evidently determined that, here, the potential for harm posed by ordering the disclosure of such information outweighed the need for such information and

⁸ Respondent now asserts that, during the August 8, 2018 pre-hearing conference call, it "objected strenuously" to the admission of CTP exhibits with "redacted identification." NA at 6. While the ALJ's August 9, 2018 order memorializing the conference discussion does not address whether Respondent (represented by counsel) raised any such objection orally, Respondent did not file any objection to the completeness or accuracy of the memorialization after that conference. Moreover, the ALJ's order made clear that the parties could object to the admission of any *new or previously offered* exhibits on or before August 23, 2018. Respondent filed no written objection about any CTP exhibit filed earlier or CTP's new exhibits 15 and 16. *See* ALJ's August 28, 2018 Order, at 1 (noting no objection was raised concerning CTP's exhibits 15 and 16). Respondent does not now assert that the August 28, 2018 Order is inaccurate.

⁹ The ALJ was bound to follow the Part 17 regulations, not the Federal Rules, which, like the Federal Rules of Evidence, are applied in federal courts. Accordingly, the ALJ committed no error in not looking to the Federal Rules. The Board has stated, however, that the Federal Rules, such as Fed. R. Civ. P. 56's summary judgment standard, may be applied if appropriate. *See, e.g., Pinebelt Ass'n for Cmty. Enhancement*, DAB No. 2611, at 3 n.3 (2014); *John A. Hartman, D.O.*, DAB No. 2911, 6-8 (2018). In any event, even were we to assume that the ALJ could or should have looked to the Federal Rules here, Respondent does not articulate how they support its position that the ALJ erred in not ordering CTP to release information revealing the minor's identity, or in admitting CTP exhibits 15 and 16. Nor does Respondent explain why the Federal Rules support its position that the ALJ could not later permit the parties to submit additional exhibits after she issued the limited protective order.

accordingly determined not to order CTP to release that information. We see no legal error or abuse of discretion in the ALJ's issuance of a protective order.

Respondent takes issue with the ALJ's statement that, while Inspector Laurin did not directly witness the alleged sale, the regulations do not require "a direct eyewitness." NA at 3 (quoting ALJ Decision at 6 n.2). It asserts that the ALJ did not "accurately apply" *TOH*, which is distinguishable from Respondent's case because, in *TOH*, the FDA inspector testified as an "eyewitness," and that this difference should be the basis for allowing Respondent to have "more information" about the minor. *Id.* First, the ALJ did not err in stating that the FDA inspector is not required to have directly witnessed the transaction to support CTP's allegations of an illegal sale. No law or regulation requires such evidence. Second, nowhere in *TOH* did the Board state, let alone suggest, that where the inspector does not testify at hearing, that could or should be reason for an ALJ to deny CTP's motion for a protective order or otherwise prohibit or restrict CTP's withholding of information revealing the minor purchaser's identity. Respondent points to no Board decision or any other authority supporting the proposition that where the FDA inspector does not testify at hearing, an ALJ who permitted CTP to withhold information about the minor's identity erred or abused his or her discretion or that the retailer in that circumstance would be entitled to have information revealing the minor purchaser's identity. Third, Respondent disregards that it could have cross-examined Inspector Laurin at hearing if it had any concern about the reliability or credibility of the inspector's written direct testimony for any reason, but chose not to do so.

Finally, Respondent's arguments about the purported need for information revealing the undercover minor's identity to confirm whether the individual I.W. and B.W. referred to as a "young male" was actually FDA's female minor purchaser are aimed at this: to discredit CTP's evidence that Respondent illegally sold tobacco to a minor. Respondent's theory seems to be that, if the minor's identity were to be revealed and I.W. and B.W. are able to state that the individual they identified as a "young man" was actually the female undercover minor, then there would be some basis to cast doubt on whether an illegal sale to a minor actually occurred, since I.W. and B.W. both stated that an older man bought the tobacco when the "young man" was denied a sale. However, as we discussed earlier, the ALJ did not rely on the gender of the minor in reaching her decision. Nor did she need to since the competent, reliable and credible evidence on which she relied, as previously discussed, was sufficient to establish the unlawful sale of tobacco products to a minor.

II. *The ALJ did not commit the mitigation error alleged by Respondent or any other error in deciding to impose a \$5,591 CMP, a decision supported by substantial evidence.*

The Secretary must take into account “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” to determine the amount of a CMP. 21 U.S.C. § 333(f)(5)(B); *see also* 21 C.F.R. § 17.34(b) (statutory factors that may mitigate or aggravate the offense for which penalty is assessed must be considered). The regulations similarly provide that the ALJ and Board “shall evaluate any circumstances that mitigate or aggravate the violation and shall articulate in their opinions the reasons that support the penalties and assessments imposed.” 21 C.F.R. § 17.34(a). In addition, the ALJ and Board may consider “any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.” *Id.* § 17.34(c); *Vasudevay LLC, d/b/a Town News and Tobacco*, DAB No. 2746, at 4 (2016).

The ALJ considered the statutory factors to determine whether a \$5,591 penalty was reasonable and appropriate. ALJ Decision at 8-10. Regarding the “nature, circumstances, extent and gravity of the violations,” the ALJ found 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.” *Id.* at 9. The ALJ also found that Respondent’s “repeated inability . . . to comply with federal tobacco regulations is serious in nature . . .” *Id.* The ALJ next found that Respondent did not argue “that it does not have the ability to pay the \$5,591 CMP,” and that it presented no evidence that the proposed penalty would affect its “ability to continue to do business” even though Respondent was given “several opportunities” to submit “any financial information on its ability to pay.” *Id.* at 8, 9. The ALJ considered the “history of prior violations,” concluding that Respondent’s “continued inability to comply with the federal tobacco regulations calls for a more severe penalty.” *Id.* at 9. The ALJ also considered the “degree of culpability,” finding Respondent “fully culpable for all five violations of the Act and its implementing regulations.” *Id.* at 10. Respondent does not challenge these ALJ findings.

The ALJ also considered Respondent’s assertion, made in its pre-hearing brief at 3, that its cashier uses “an FDA-sponsored cell phone app to scan IDs,” but found that “Respondent failed to provide any evidence of the remedial measures it has taken or evidence to show when Respondent took such measures.” *Id.* Moreover, the ALJ also found, Respondent had “ample opportunity” to return to compliance, but did not do so. *Id.* Thus, the ALJ concluded, “there is no basis in the record . . . to find mitigating factors” that would permit a reduction of the \$5,591 penalty the ALJ found “proportional and appropriate.” *Id.*

Respondent now asserts that the penalty should be lowered to \$500 because it submitted to the ALJ “evidence of training and signage . . . that show[s] a commitment to proper ID activity at the point of sale.” NA at 8 (citing Resp. Exs. 1-5). Respondent then states that the declaration of I.W. is proof of such training and signage and that “[n]o other incident has been reported after this case in November 2017.” *Id.*

Contrary to Respondent’s assertion, the declaration of I.W. does not even address training and signage, much less provide proof of same. *See* Resp. Ex. 2. Respondent’s witness lists (initial and revised) proposed a witness, Respondent’s owner, who purportedly would testify “to displays and training of store employees regarding sale of tobacco products and the ID requirement.” *See* Civil Remedies Docket Numbers 14 and 20. However, Respondent did not call the witness to testify. While Respondent later proffered the written declaration of this proposed witness who asserted, “My store policy, displays and training are designed to prevent tobacco sales without proper ID[.]” Respondent submitted no evidence that clearly supports this bare assertion. Resp. Ex. 4. Although Respondent’s Exhibit 5 contains a photograph of the cashier window that shows a sign stating “all tobacco sales requires [sic] ID” and another indicating that the store checks identification and bearing the words “Under 18 No Tobacco,” it is not clear when this photograph was taken. However, even assuming the signs shown in the photograph were on display before and on the inspection date, we do not see how that alone would be a mitigating factor when the evidence establishes that Respondent sold tobacco to a minor, and without checking his or her age, on multiple dates, including November 30, 2017.¹⁰

In any case, Respondent does not show why the signs on the cashier window would warrant a reduction in the CMP amount. Moreover, Respondent does not otherwise raise any argument challenging the ALJ’s determination that \$5,591 is a “proportional and appropriate” penalty (ALJ Decision at 10). We find the ALJ’s determination lawful and supported by substantial evidence in the record.

¹⁰ Even if we had concluded that the ALJ erred in not addressing whether the signs on the window support any mitigating factor, we would also have concluded that the error was harmless and thus not a basis for disturbing the ALJ’s determination on the penalty amount since, as the ALJ determined, and we agree, Respondent committed five violations of selling tobacco products to minors without verifying that the purchasers were at least 18 years old, within a 36-month period. *See* 21 C.F.R. § 17.48; *Deli-Icious Catering, Inc. d/b/a Convenient Food Mart*, DAB No. 2812, at 10, 12 n.8 (2017) (relying on 21 C.F.R. § 17.48’s harmless error standard in determining that the ALJ did not err in striking certain evidence as not compliant with 21 C.F.R. § 17.37(b) and the ALJ’s instructions for filing exhibits).

Conclusion

For the foregoing reasons, we affirm the ALJ Decision.

_____/s/
Sheila Ann Hegy

_____/s/
Constance B. Tobias

_____/s/
Susan S. Yim
Presiding Board Member