Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Three Star Market, Inc. d/b/a Three Star Market
Docket No. A-18-62
Decision No. 2906
October 26, 2018

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Three Star Market, Inc. d/b/a Three Star Market (Respondent) appeals the March 28, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a six-month No-Tobacco-Sale Order (NTSO) against Respondent for seven repeated 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. *Three Star Market, Inc. d/b/a Three Star Market*, DAB TB2545 (2018) (ALJ Decision). The ALJ issued his decision following a hearing on an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) in which CTP alleged that during an FDA inspection on January 21, 2017, Respondent's staff sold a package of cigarettes to a person younger than 18 years of age. The Complaint also alleged that Respondent previously sold tobacco products to a minor, and failed to verify the age of a purchaser via photographic identification, on July 4, 2013, February 1, 2014, November 20, 2014, and August 27, 2015. The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for imposition of a six-month NTSO.

On appeal, Respondent argues that its due process rights were violated, and that a six-month NTSO is inappropriate. For the reasons explained below, we reject Respondent's arguments and affirm the ALJ Decision.

Applicable Law

On June 22, 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA), which 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 "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 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 section 387f(d) of the Act. *Id*. § 387c(a)(7)(B). Congress authorized the Secretary of Health and 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 provide that "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age." 21 C.F.R. § 1140.14(a)(1). They also require retailers "to verify by means of photographic identification containing the bearer's date of birth that no purchaser of the [tobacco] products is younger than 18 years of age," except that "[n]o such verification is needed for any person over the age of 26[.]" *Id*. § (a)(2)(i).[1]

CTP may seek to impose civil money penalties (CMPs) against "any person who violates a requirement of [the Act] which relates to tobacco products . . . ." 21 U.S.C. § 333(f)(9). CTP may also seek to impose a NTSO (alone or in addition to a CMP) when it finds "that a person has committed repeated violations of restrictions promulgated under section 387f(d) . . . at a particular retail outlet . . . ." *Id*. § 333(f)(8). "Repeated violations" is defined as "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation. . . ." TCA § 103(q)(1)(a); *see also* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3, 5-6, *available at* https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.

A person is entitled to a hearing before a NTSO is entered. 21 U.S.C. § 333(f)(8). The Act does not specify the duration of a NTSO but does specify the factors that must be considered in determining the length of a NTSO: "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." *Id*. § 333(f)(5)(B). CTP

[1] At the time of the FDA inspections leading to Respondent's prior violations, these regulations were codified at 21 C.F.R. 1140.14(a) and (b). Effective August 8, 2016, the regulations were recodified without any substantive change to the sections to which we cite. 81 Fed. Reg. 28,973, 28,974, 29,103 (May 10, 2016); *see* https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf.

policy guidelines establish 6 months as the maximum NTSO duration for a retailer's second NTSO. *See* Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order (August 2015) at 4, available at http://www.fda.gov/downloads/TobaccoProducts/Labeling/ RulesRegulationsGuidance /UCM460155.pdf (FDA Guidance).

The regulations permit a retailer to appeal a NTSO 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 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 (which the regulations refer to as the "initial decision") to the DAB. 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. *Id*. § 17.47(j).

Case Background[2]

1. The Complaint and the Hearing

On March 17, 2017, CTP served a Complaint (dated March 16, 2017) on Respondent at its place of business, 19650 Schoenherr Street, Detroit, Michigan 48205. CRD Docket (Dkt.) Entries 1, 1a, 1b. The Complaint sought to impose a NTSO as a remedy for seven repeated violations of FDA's tobacco regulations over a period of 36 months. Complaint ¶ 1. The Complaint alleged that on January 21, 2017, an FDA-commissioned inspector inspected Respondent's retail establishment and found that Respondent impermissibly sold tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a)(1). *Id*. ¶ 6. The Complaint specifically alleged that during the inspection, "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on January 21, 2017 at approximately 1:28 PM." *Id*.

[2] 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.

In addition to charging Respondent with the alleged violations found during the January 21, 2017 inspection, the Complaint noted that the CRD had closed two prior CMP actions and one prior NTSO action involving complaints filed by CTP against Respondent. ALJ Decision at 2-3; Complaint ¶¶ 8-11. In the three prior actions, Respondent admitted to selling tobacco products to a minor and failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth on July 4, 2013, February 1, 2014, November 20, 2014, and August 27, 2015.[3] *Id*. Respondent "expressly waived its right to contest" the violations in subsequent actions. *Id*.

On April 17, 2017, Respondent filed an Answer to the Complaint. CRD Dkt. Entry 5. On April 21, 2017, the ALJ issued an Acknowledgment and Pre-hearing Order (APHO) which acknowledged receipt of the Answer and established procedural deadlines. ALJ Decision at 2; CRD Dkt. Entry 6. On June 12, 2017, CTP filed a motion for a protective order limiting the scope of discovery and providing that certain discovery not be had. CRD Dkt. Entry 8. On July 10, 2017, CTP filed a motion to compel discovery. CRD Dkt. Entry 10. The ALJ issued a protective order on July 28, 2017, and an order granting CTP's motion to compel on August 2, 2017. CRD Dkt Entries 13, 14. On September 14, 2017, CTP filed a pre-hearing brief, a list of proposed witnesses and exhibits and 21 numbered exhibits. CRD Dkt. Entries 15, 15a-15v. On October 5, 2017, Respondent filed a pre-hearing brief (R. Pre-Hearing Br.), a list of proposed witnesses and exhibits, and one exhibit consisting of eleven photographs. CRD Dkt. Entries 16, 16a, 17.

In its pre-hearing brief, Respondent argued that a six-month NTSO is "inappropriate in light of the nature, circumstances, extent, and gravity of the violation or violations," and asserted that its "violations are not that serious in nature as they do not contravene FDA's efforts to protect minors from the multiple adverse health effects associated with tobacco use." R. Pre-Hearing Br. at 5. Respondent argued that the violations were "a sharp example of targeting small businesses in depressed areas…" *Id*. at 5-6. Respondent asserted that the undercover minor "looked older, acted older and intentionally confused a low level employee." *Id*. at 6. Respondent asserted that it hired new personnel and implemented new safeguards to prevent a sale to a minor from happening in the future. *Id*. at 5, 6. Respondent also argued that a six-month NTSO would have a negative effect on Respondent's ability to continue to do business because customers would develop new purchasing habits by purchasing tobacco products elsewhere. *Id*. at 5.

[3] CTP labels each violation that occurred on July 4, 2013 as an "original violation" and each violation that occurred on February 1, 2014, November 20, 2014 and August 27, 2015 as a "repeated violation" for the purposes of seeking a NTSO. *See* Complaint ¶ 1 (and the table that follows).

The ALJ held a pre-hearing conference on November 2, 2017, at which the ALJ "explained that the credibility of the minor is not relevant here because CTP is relying on the inspector's testimony only." Amended Order Scheduling In-Person Telephone Hearing [CRD Dkt. Entry 20] at 1. On January 9, 2018, the ALJ held a hearing via telephone. During the hearing, the ALJ admitted the party's exhibits and heard cross-examination testimony from the inspector who conducted the January 21, 2017 inspection at Respondent's establishment (Inspector Ramsey). ALJ Decision at 1; Hearing Transcript [CRD Dkt. Entry 21] at 5-29. CTP and Respondent each filed post-hearing briefs on February 28, 2018. CRD Dkt. Entries 24, 25. In its post-hearing brief, Respondent reiterated the arguments made in its pre-hearing brief, and noted that the undercover minor was "never even allowed" to testify. R. Post-Hearing Brief at 2.

2. The ALJ Decision

The ALJ imposed a six-month NTSO on Respondent after concluding that "[t]he evidence supports CTP's allegations" that Respondent violated 21 C.F.R. § 1140.14(a)(1) on January 21, 2017 by selling tobacco products to a minor. ALJ Decision at 3. The ALJ, relying on Inspector Ramsey's testimony and corroborating photographs, found that Respondent "committed a total of seven repeated violations during a period of less than 36 months." *Id*. at 4. The ALJ found that Respondent offered no evidence to refute CTP's evidence, and rejected as speculative Respondent's argument that the minor purchaser looked older than her actual age. *See id*. The ALJ also rejected, for lack of evidence, Respondent's argument that its employee was entrapped into selling cigarettes to the minor, concluding there was no evidence "that the sale of cigarettes on January 21, 2017, was anything other than an arm's length transaction between the clerk at Respondent's establishment and the minor purchaser." *Id*. at 3. The ALJ rejected Respondent's argument that he should have compelled CTP to produce the minor purchaser as a witness, finding that "although the minor's testimony would be relevant, she is not a witness in this case nor is her testimony necessary" because Inspector "Ramsey personally witnessed the unlawful sale on January 21, 2017, and produced corroborating evidence consisting of photographs of the cigarettes that Respondent sold to the minor on that date." *Id*. at 3-4.

The ALJ next addressed whether a NTSO for a duration of six months is reasonable. The ALJ ascribed a "dual purpose" to NTSOs: 1) "to protect the public from a retailer that has shown indifference to regulatory requirements through repeated violations of those requirements"; and 2) "to deter retailers from unlawfully selling tobacco products." *Id*. at 4. The ALJ found that Respondent's previous violations – which subjected Respondent to two civil money penalties and a 30-day NTSO – "clearly have done nothing to deter Respondent." *Id*. The ALJ concluded that a six-month NTSO "is necessary because no other remedy has worked to deter Respondent from making

unlawful sales." *Id*. The ALJ rejected, for lack of evidence, Respondent's argument that a six-month NTSO "will effectively put [Respondent] out of business" (citing R. Post-Hearing Br. at 1-3), and Respondent's argument that it is "the victim of targeted inspections… aimed at minority business proprietors in poor communities" (citing *id*. at 2-3; R. Pre-Hearing Br. at 5-6). ALJ Decision at 4. The ALJ also rejected Respondent's assertion that the penalty should be mitigated due to the "numerous signs posted in [Respondent's] store that announce Respondent will not sell tobacco products to minors" because it was unclear whether Respondent's signs were posted prior to the date of the most recent violation, and because the signs were "meaningless" as long as Respondent failed to "actually verify its customers' ages." *Id*. at 4-5 (citing R. Ex. 1).

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*.

Analysis

In its Request for Review (RR), Respondent disagrees with the ALJ Decision on two grounds. First, Respondent contends that the ALJ violated Respondent's due process rights by not compelling the minor to appear at the hearing to be subject to cross-examination. RR at 6-8. Second, Respondent contends that a six-month NTSO is inappropriate because the violations "are not that serious in nature," but rather an example of inspectors "targeting" small businesses that service low income and minority areas. *Id*. at 5-6. Respondent also contends that a NTSO for a duration of six months would hurt Respondent's ability to continue to do business, and that Respondent's efforts to prevent future violations should mitigate the penalty. *Id*. at 6, 10. For the following reasons, we conclude that Respondent's arguments are meritless.

I. *The ALJ did not violate Respondent's due process rights by not compelling the minor to testify.*

Respondent argues that the ALJ should have "compelled" the undercover minor involved in the January 21, 2017 unlawful sale to testify. *Id*. at 6-8. Respondent asserts that its "constitutional right to confront" the minor was violated, and expounds on legal precedent regarding a party's right to cross-examine witnesses. *Id*. at 7-9. Respondent's arguments are meritless. As a preliminary matter, Respondent's invocation of the "Confrontation Clause" attempts to inject a criminal procedural issue into this administrative proceeding. The Sixth Amendment to the United States Constitution

provides that, "in all *criminal prosecutions*, the accused shall enjoy the right . . . to be confronted with the witnesses against him." (Emphasis added). Respondent cites no authority to support its argument that the constitutional right to confront a witness should be extended to administrative hearings, and in fact acknowledges that "[t]here is some legal authority to suggest that the Confrontation Clause does not apply to administrative hearings . . . [.]" RR at 8; *see, e.g., Austin v. United States*, 509 U.S. 602, 608 (1993) (stating "[t]he protections provided by the Sixth Amendment are explicitly confined to criminal prosecutions") (internal quotation marks omitted); *Golden Living Ctr. – Frankfort v. Sec'y of Health & Human Servs.*, 656 F.3d 421, 426 (6th Cir. 2011) (holding that the petitioner had "not shown that the Confrontation Clause applie[d]" to the case), *aff'g Golden Living Ctr. – Frankfort*, DAB No. 2296 (2009).

While the Sixth Amendment due process protections do not apply in this case, the governing regulations afford a party the opportunity to cross-examine witnesses "as may be required for a full disclosure of the facts." 21 C.F.R. § 17.37(d). Respondent's argument that it should have been allowed to "cross-examine" the minor, however, is negated by the fact that CTP did not offer the direct testimony of the minor. In reaching his conclusions, the ALJ relied instead on Inspector Ramsey's testimony that she "personally witnessed the unlawful sale on January 21, 2017," and "corroborating evidence consisting of photographs of the cigarettes that Respondent sold to the minor on that date." ALJ Decision at 4; *see also* CTP Ex. 15, at 2-3 (Inspector Ramsey testified that she "had an unobstructed view of the sales counter and" the minor, and "observed [the minor] purchase a package of cigarettes from an employee at the establishment."). Thus, the ALJ concluded, the minor was "not a witness in this case" and therefore was not subject to cross-examination. ALJ Decision at 4. Moreover, Respondent's argument that "[a] party opposing an offer of hearsay evidence in an administrative proceeding is entitled to an opportunity to cross-examine the declarant" (RR at 9) is irrelevant because Respondent did not identify, nor did the ALJ rely on testimony that would constitute hearsay.[4] Respondent was afforded the opportunity to cross-examine, and did cross-

[4] The Federal Rules of Evidence (FRE) defines hearsay as:

> Hearsay. "Hearsay" means a statement that:
> (1) the declarant does not make while testifying at the current trial or hearing; and
> (2) a party offers in evidence to prove the truth of the matter asserted in the statement.

FRE Rule 801(c). The ALJ and the Board are not bound by the FRE, but may apply the FRE when appropriate. *See* 21 C.F.R. § 17.39(b) ("Except as provided in this part, the presiding officer [the ALJ] shall not be bound by the [FRE]. However, the presiding officer may apply the [FRE] 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) ("the rules governing this proceeding provide that the ALJ is not bound by the [FRE] and, as the Board has long observed, hearsay is admissible in administrative proceedings generally and can be probative on the truth of the matter asserted, where sufficient indicia of reliability are present").

examine, Inspector Ramsey, who testified solely to her personal observations. *See* CTP Ex. 1; Hearing Transcript at 8-27; *see also Deli-Icious Catering, Inc. d/b/a Convenient Food Mart*, DAB No. 2812, at 13 (2017) ("[T]he inspectors' testimony on which the ALJ relied was not hearsay because they testified to their personal observations.").

Respondent argues that its "theory of [d]efense rested on" the minor's testimony (RR at 8) – a defense based on Respondent's assertion that its employee was entrapped into selling cigarettes to the minor. *See id*. at 7 ("The inspector used a person who looked older, acted older and intentionally confused a low level employee at Respondent's business."). Respondent asserts that, had the ALJ "compelled"[5] the minor to testify, "Respondent would have established that the minor was hand selected and trained to act confident and act as a much older person would act," and "other issues like 'what actually happened' would have been exposed." *Id*. at 7. Respondent has not shown, however, that a defense of entrapment is even available in this proceeding. The Board has previously found that "entrapment would not appear to be available in a federal enforcement action for sale of tobacco products to minors." *TOH, Inc. d/b/a Ridgeville Serv. Ctr.*, DAB No. 2668, at 14-15 (2015) (quoting *Rodriguez v. United States*, 534 F. Supp. 370, at 373-74 (D.P.R. 1982) ("According to the federal jurisprudence, the defense of entrapment is apparently non-available in the federal civil litigations and is limited only to criminal actions.")).[6] Moreover, Respondent has not provided any documentary evidence or witness testimony to support its assertions, or shown that its entrapment defense is anything more than speculation. *See* ALJ Decision at 3 (Respondent "has offered no evidence to show that the sale of cigarettes on January 21, 2017, was anything other than an arm's length transaction between the clerk at Respondent's establishment and the minor purchaser"). On the contrary, the record on which the ALJ made his decision shows that the minor had a valid ID showing her age. *Id*. (citing CTP Ex. 15 (Inspector's declaration) ¶ 9 (stating, in part, that she, the inspector, confirmed that the minor had in her possession a photographic ID showing her "actual date of birth" before entering Respondent's establishment)). Respondent's clerk was required to check the ID

[5] Respondent does not identify the authority under which the ALJ could "compel" the minor to testify. As we have already explained, the minor was not a "witness" subject to cross-examination. The regulations, however, provide that a party can file a written request for the ALJ to issue a subpoena requiring an individual to appear and testify at the hearing upon a showing of good cause. 21 C.F.R. § 17.27(a), (c). While Respondent asserts that it requested the minor's testimony during the November 2, 2017 prehearing conference call (RR at 7), there is nothing in the record to indicate that Respondent filed a written request for a subpoena in accordance with the regulations.

[6] The Board in *TOH* ultimately found that it "need not, however, resolve the question of whether an entrapment defense might ever lie in a tobacco enforcement proceeding," because Respondent had "not described, much less proven, that either minor engaged in any trickery or dishonesty to induce the illegal sales" and had thus "not proven the elements of such a defense." *TOH*, DAB No. 2668, at 15; *see also J. Peaceful, L.C. d/b/a Town Market*, DAB No. 2742, at 12 (2016).

pursuant to section 1140.14(a)(2)(i), a regulation that the Board has found "do[es] not incorporate any 'appearance' or 'judgment' standard." *Deli-Icious Catering*, DAB No. 2812, at 11.[7] Nonetheless, Respondent's clerk willingly sold cigarettes to the minor. ALJ Decision at 3 (citing CTP Ex. 15 ¶ 10). In addition, Inspector Ramsey testified on cross-examination that all undercover minors are instructed to dress appropriately (Hearing Transcript at 14, 27), and that the minor in question "looks like a teenager." *Id*. at 22. Therefore, even if we were to consider Respondent's entrapment defense, Respondent has not shown that the minor's testimony would be likely to support its argument that the minor engaged in trickery or dishonesty to induce an illegal sale.

In sum, Respondent has failed to show that its due process rights were violated by the ALJ not compelling the minor to testify.

II. *The ALJ did not err in imposing a NTSO for a duration of 6 months.*

Before the Board, Respondent maintains that a six-month NTSO is inappropriate, and reiterates many of the same arguments considered and rejected by the ALJ on this issue. RR at 4-6. When determining the duration of a NTSO, the Act requires the Secretary 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 such prior violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 333(f)(5)(B). The ALJ considered and discussed circumstances relating to these factors, as well as the arguments raised by Respondent, and concluded that a six-month NTSO is "reasonable" and "necessary." ALJ Decision 4-5. Regarding the "nature, circumstances, extent, and gravity of the violations," the ALJ found Respondent's conduct to be "egregious," and noted that "Respondent persisted in selling tobacco products to a minor after receiving a warning from CTP and after having been subject to two civil money penalties and an NTSO." *Id*. at 4. The ALJ rejected Respondent's argument that it is the victim of targeted inspections, stating that Respondent "offered no evidence to substantiate" its claim. *Id*. On appeal, Respondent renews its arguments regarding this issue, stating that it was the victim of inspectors "targeting small businesses in depressed areas where finding intelligent help is very difficult." RR at 5. Respondent further reiterates that low income and minority "businesses are spot checked more often than the white suburbs to the north." *Id*. at 5-6. However, while Respondent argues that the ALJ "incorrectly suggest[ed] that no evidence was presented" regarding its assertions (RR at 6), Respondent does not identify,

[7] Neither Inspector Ramsey's testimony, nor the corroborating evidence relied on by the ALJ, indicates whether the clerk verified the minor's age by means of photographic identification containing the bearer's date of birth. *See* CTP Ex. 15; Hearing Transcript at 8-29.

nor do we find, any evidence in the record supporting its assertions of disparate treatment. Thus, we conclude that Respondent has failed to prove that it is the victim of targeted inspections, or that businesses in "low income and minorit[y]" neighborhoods are "spot checked" more often by CTP inspectors.

The ALJ discussed Respondent's "history of prior violations," noting that "Respondent repeatedly violated regulations governing the sale of tobacco products to minors, committing a total of seven repeated violations during a period of less than 36 months." ALJ Decision at 4. The ALJ also considered the "effect on [Respondent's] ability to continue to do business," finding that Respondent "has not offered any evidence to substantiate" its claim "that a six-month NTSO will effectively put it out of business." *Id*. (citing R. Post-Hearing Br. at 1-3). Respondent continues to argue on appeal that a six-month NTSO will hurt Respondent's business (RR at 6), but has not cited to any evidence in the record that the ALJ may have overlooked. Thus, although Respondent disagrees with the ALJ's finding and weighing of this factor, there is no basis for Respondent's assertion that the ALJ "side stepped" the issue "and did not give it full consideration." *Id*.

The ALJ also considered Respondent's "additional arguments" for mitigating the penalty, writing in relevant part:

> Finally, Respondent asserts that the penalty should be mitigated by its efforts to prevent unlawful tobacco sales. *See* [R. Informal Br.] at 3. To that end, it points to numerous signs posted in its store that announce that Respondent will not sell tobacco products to minors. *See* Respondent's Ex. 1. It is unclear whether these signs predated the January 21, 2017 unlawful sale, but even if they did, they establish no basis for mitigation. Signs announcing an establishment's intent not to sell tobacco products to minors are meaningless if the establishment fails to follow through and actually verify its customers' ages.

ALJ Decision at 4-5.[8] While Respondent asserts that the ALJ "glossed over" its additional arguments "by recklessly claiming that Respondent might have made these changes before the date [o]f the last ticket" (RR at 10), we find that the ALJ gave full and fair consideration to the evidence before him. The only evidence Respondent cited to

[8] 21 U.S.C. § 333(f)(5)(B) does not expressly mention the terms "mitigation" or "mitigating factors." We construe the ALJ's consideration of Respondent's "additional arguments" to be under the "other matters as justice may require" factor set forth in that statute. *See Zoom Mini Mart, Inc.*, DAB No. 2894 at 16 (2018) ("We note that section 333(f)(5)B) does not expressly mention "mitigating factors." Nonetheless, the ALJ considered under the "substantial justice" factor set forth in that statute the circumstances that Respondent alleged were "mitigating factors.").

was the set of unmarked photos that purportedly prove "remedial actions" found in R. Ex. 1, actions which the ALJ considered and rejected for purposes of mitigating the penalty regardless of whether they were implemented after January 21, 2017. We also reject Respondent's arguments that the ALJ should have considered additional mitigating factors. Respondent asserts that it "made significant changes to person[nel] and training and protocol[,]" but does not detail what specific changes were made. Similarly, Respondent states that it "implemented safeguards that would prevent this from ever happening again[,]" but it is unclear whether these "safeguards" differ from the "remedial actions" in R. Ex. 1 that the ALJ considered and rejected. Moreover, Respondent states that it should "be given substantial credit for the fact that over the last 10 months there have been no violations . . .[,]" but provides no authority or explanation for how this somehow reduces Respondent's culpability for the January 21, 2017 violation, its seventh within 36 months. In sum, Respondent has failed to demonstrate that the six-month NTSO warrants mitigation.

The six-month NTSO the ALJ found appropriate is consistent with the statute and FDA Guidance given Respondent's seven repeated violations of the regulations at 21 C.F.R. Part 1140 within a 36-month period. 21 U.S.C. § 333(f)(8); FDA Guidance at 3-4. As we have discussed, the ALJ addressed the factors he was required to consider, including the "additional arguments" regarding mitigation made by Respondent. The ALJ came to his conclusion by following the applicable authority found in the Act and TCA, authority by which we are bound. *See J. Peaceful*, DAB No. 2742, at 15 (quoting 21 C.F.R. § 17.19(c) ("presiding officer does not have the authority to find Federal statutes or regulations invalid")). We therefore find no basis to disturb the ALJ's conclusion that a NTSO for the duration of six months is appropriate.

Conclusion

For the foregoing reasons, we affirm the ALJ Decision in its entirety and sustain the six-month NTSO entered by the ALJ.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Christopher S. Randolph
Presiding Board Member