Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Zoom Mini Mart, Inc.
Docket No. A-18-45
Decision No. 2894
September 13, 2018

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Zoom Mini Mart, Inc. (Respondent) appeals the February 14, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a 30-calendar-day No-Tobacco-Sale Order (NTSO) against Respondent for six 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. *Zoom Mini Mart, Inc.*, DAB TB2441 (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 March 10, 2016, Respondent's staff 1) sold a package of cigarettes to a person younger than 18 years of age and 2) did not verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. 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 December 31, 2013, July 9, 2014 and April 18, 2015. The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for imposition of a 30-calendar-day NTSO.

On appeal, Respondent argues that the ALJ erred in evidentiary rulings and failed to consider mitigating factors when determining the length of the NTSO. 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 at issue here, 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 30 calendar days as the maximum NTSO duration for a retailer's first 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 February 2, 2017, CTP served a Complaint (dated February 1, 2017) on Respondent at its place of business, 14545 Plymouth Road, Detroit, Michigan 48227. ALJ Decision at 2; CRD Docket (Dkt.) Entries 1, 1a, 1b. The Complaint sought to impose a NTSO as a remedy for six repeated violations of FDA's tobacco regulations over a period of 36 months. ALJ Decision at 1; Complaint ¶ 1. The Complaint alleged that on March 10, 2016, an FDA-commissioned inspector inspected Respondent's retail establishment and found the following violations of the Act and regulations: 1) impermissibly selling tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a)(1) and 2) failing to verify that the purchaser was 18 years of age or older by means of photographic identification containing a date of birth in violation of 21 C.F.R. § 1140.14(b)(2)(i). ALJ

[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.

Decision at 1; Complaint ¶ 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 March 10, 2016 at approximately 6:13 PM" and that "the minor's identification was not verified before the sale, as detailed above, on March 10, 2016, at approximately 6:13 PM." *Id*. CTP filed a copy of the Complaint with the CRD to initiate the proceedings leading to this appeal. ALJ Decision at 2.

In addition to charging Respondent with the alleged violations found during the March 10, 2016 inspection, the Complaint noted that the CRD had closed two prior CMP actions involving complaints filed by CTP against Respondent. *Id*. at 2 (citing Complaint ¶¶ 1, 6, 9-12 and Informal Brief of Complainant at 1-2). In the two prior CMP 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 December 31, 2013, July 9, 2014 and April 18, 2015.[3] *Id*. at 11 (citing Complaint ¶¶ 9-10). Respondent "expressly waived its right to contest" the violations in subsequent actions. *Id*.

On March 2, 2017, Respondent filed an Answer to the Complaint. *Id*. at 2; CRD Dkt. Entry 3a. In the Answer, Respondent denied the allegations of liability. ALJ Decision at 6 (citing Answer ¶¶ 1-4, 6, 9-12). Respondent also argued, *inter alia*, that CTP is seeking a NTSO for violations that pre-date the adoption of NTSOs as a penalty. *Id*. (citing Answer ¶¶ 12, 15). On March 7, 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 4. The APHO stated that each party must file and serve all documents electronically by DAB E-File (the DAB's electronic filing system). APHO at 2. The APHO also stated that each party's pre-hearing exchange must be filed and include a copy of each proposed exhibit and the complete written direct testimony of any proposed witness. APHO at 4, 6. On June 13, 2017, CTP filed a pre-hearing brief, a list of proposed witnesses and exhibits and 21 numbered exhibits, including the sworn written direct testimony of the inspector who documented the alleged March 10, 2016 violations (Inspector Bishop). ALJ Decision at 2; CRD Dkt. Entries 8, 8a-8v. On July 3, 2017, Respondent filed a pre-hearing brief and a list of proposed witnesses and exhibits.[4] ALJ Decision at 2; CRD Dkt. Entries 9, 10. Respondent's submission did not include any sworn written direct testimony or any of its proposed exhibits. ALJ Decision at 2.

[3] CTP labels each violation that occurred on December 31, 2013 as an "original violation" and each violation that occurred on July 9, 2014, April 18, 2015 and March 10, 2016 as a "repeated violation" for the purposes of seeking a NTSO. *See* ALJ Decision 2; Complaint ¶ 1 (and the table that follows).

[4] Respondent's List of Witnesses and Exhibits listed 4 proposed witnesses and 8 proposed exhibits. CRD Dkt. Entry 10.

In its pre-hearing brief, Respondent argued that a NTSO is inappropriate because the violations were "a result of a renegade employee who failed to do as he was trained." *Id*. at 6 (quoting Respondent's Informal Brief ¶ 5) (internal quotation marks omitted). Respondent also asserted that management provides training to its staff, posts signs "stressing that minors are not to buy tobacco[,]" and uses a point of sales system that requires the clerk to ask for a birthdate before tobacco product sales, and that the manager's gas stations "participate in the City of Detroit Green Light Program, which requires participants to invest in cameras that are monitored by the Detroit Police Department." *Id*. Respondent also argued that Inspector Bishop focused on this particular merchant because he made an unsuccessful undercover buy attempt at a different location run by the same manager thirty minutes prior to the alleged violations. *Id*.

The ALJ held a pre-hearing conference on August 3, 2017. *Id*. at 3. The ALJ noted during the pre-hearing conference that Respondent had not filed the written direct testimony of its proposed witnesses or copies of its proposed exhibits. *Id*. The ALJ informed the parties that Inspector Bishop was the only witness who could appear for cross-examination at the hearing because his written direct testimony was the only sworn written direct testimony filed by the pre-hearing exchange deadlines. *Id*. Respondent's counsel stated that counsel had submitted copies of the proposed exhibits and witness testimony, that counsel did not know why the documents were not in the file, and that counsel desired to file a motion regarding Respondent's proposed witnesses and exhibits. *Id*.

On August 4, 2017, the ALJ issued an Order to Show Cause Why Respondent's Witnesses and Exhibits were not Submitted in Accordance with 21 C.F.R. §§ 17.25(a), 17.37(b) (OSC). *Id*.; CRD Dkt. Entry 12. In the OSC, the ALJ instructed, "Respondent must demonstrate that **extraordinary circumstances** prevented compliance with the [APHO] and 21 C.F.R. §§ 17.25(a), 17.37(b)." ALJ Decision at 3 (quoting OSC at 2 (emphasis in original)). On August 14, 2017, Respondent filed a Motion for Leave to Call Witnesses and Have Exhibits Admitted at the Hearing (Motion for Leave), and attached twelve proposed exhibits, including a sworn statement from Respondent's general manager, Nabil Hizam (Hizam's Statement), who had been listed as a proposed witness on Respondent's previously filed witness list. *Id*.; CRD Dkt. Entries 10, 13, 13a-13l. CTP filed a response in opposition to Respondent's Motion for Leave on August 29, 2017. ALJ Decision at 3; CRD Dkt. Entries 14, 14a-14d. On September 8, 2017, the ALJ issued an order denying Respondent's Motion for Leave (ODM) on the ground that Respondent did not demonstrate that its failure to comply with the pre-hearing exchange rules, as set forth in the APHO and 21 C.F.R. §§ 17.25(a) and 17.37(b), was due to extraordinary circumstances. ALJ Decision at 3; CRD Dkt. Entry 15.

On November 7, 2017, the ALJ held a hearing via telephone, at which he admitted CTP's exhibits and heard cross-examination testimony from Inspector Bishop. ALJ Decision at 4 (citing Hearing Transcript (CRD Dkt. Entry 16) at 8-14). During the cross-examination, CTP objected to, and the ALJ sustained as irrelevant, Respondent's questioning regarding an inspection conducted by Inspector Bishop at a different retail establishment under the same management on March 10, 2016 prior to the inspection of Respondent's retail establishment where the alleged violations occurred. *Id*. at 7 (citing Hearing Transcript at 10-11). CTP also objected to, and the ALJ sustained as irrelevant, Respondent's elicitation of testimony (which the ALJ noted was outside the scope of the witness's written direct testimony) regarding Inspector Bishop's previous inspections at Respondent's establishment prior to March 10, 2016. *Id*. (citing Hearing Transcript at 11-12). The ALJ did not allow the testimony of an employee of Respondent (someone other than Mr. Hizam) for whom Respondent had failed to provide written direct testimony by the pre-hearing exchange deadline. *Id*. (citing Hearing Transcript at 15). While reiterating that Respondent's proposed exhibits had not been submitted as marked exhibits by the ordered exchange date, the ALJ stated that Respondent "may argue mitigating circumstances in his post-hearing briefs pursuant to 21 C.F.R. § 17.34[]" and "clarified that [Respondent's Counsel] may make reference to the case documents in the administrative record although they are not exhibits." *Id*. (citing Hearing Transcript at 15-16).

CTP and Respondent each filed post-hearing briefs on December 28, 2017. CRD Dkt. Entries 18, 19. In Respondent's Post-Hearing Brief, Respondent admitted that the violations on March 10, 2016 occurred. ALJ Decision at 8 (citing Respondent's Post-Hearing Brief at 2). Respondent also reiterated that "an NTSO is inappropriate because the violations occurred because of a renegade employee." *Id*. (citing Respondent's Post-Hearing Brief at 3). In CTP's Post-Hearing Brief, CTP asserted that the happenings at another store are irrelevant to the current alleged violations. *Id*. (citing CTP's Post-Hearing Brief at 3). CTP also argued that "the training and efforts of Respondent at the other location, even if true and supported by admissible evidence, did not stop Respondent from selling a tobacco product to a minor and failing to verify the purchaser's age by means of photographic identification on March 10, 2016, at the 14545 Plymouth Road location." *Id*. (quoting CTP's Pre-Hearing Brief at 3) (internal quotation marks omitted).

2. The ALJ Decision

On February 14, 2018, the ALJ issued his decision imposing a 30-calendar-day NTSO against Respondent. The ALJ imposed the NTSO after concluding that CTP "provided an abundance of evidence to support" its allegations that Respondent violated 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) on March 10, 2016 by selling tobacco products to a minor

and failing to verify that the tobacco product purchaser was of sufficient age. *Id*. at 10. In reaching his conclusion, the ALJ relied on the testimony of Inspector Bishop, finding that the inspector "testified credibly about his observations during the March 10, 2016 inspection . . . ." *Id*. at 8. The ALJ found that "Respondent's Counsel failed to rebut any of Inspector Bishop's assertions regarding the March 10, 2016 violations" during cross-examination, and that "Respondent failed to provide evidence that rebuts CTP's evidence in support of its allegations . . . ." *Id*. at 8, 9. The ALJ also found that Respondent conceded in its post-hearing brief that the March 10, 2016 violations occurred. *Id*. at 9-10 (citing Respondent's Post-Hearing Brief at 2 ("On March 10, 2016 the Center for Tobacco Products utilized an undercover confidential state-contracted minor to conduct a compliance check at the location. The undercover minor was accompanied by FDA commissioned [I]nspector… Bishop. The undercover minor purchased a Newport box 100s cigarette product from a store clerk.")). The ALJ noted that, while Mr. Hizam's Statement was excluded from evidence pursuant to his September 8, 2017 Order, even if the ALJ were to consider the statement, it appears to concede that the March 10, 2016 violations occurred. *Id*. at 9 (citing Hizam's Statement at ¶ 15 ("The incident involved in this case was caused entirely by a clerk that ignored his training, and not by the store management that has made every effort to stop sales to minors . . . .")). The ALJ found that he had the authority to impose a NTSO on Respondent and, after weighing the factors listed in 21 U.S.C. §333(f)(5)(B), as well as potential mitigating factors, concluded that a NTSO for a period of 30 days was an appropriate penalty.

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*. The standard of review on an ALJ's imposition of a sanction under 21 C.F.R. § 17.35 is whether the ALJ committed an abuse of discretion. *Joshua Ranjit Inc*. *d/b/a 7-Eleven* 10326, DAB No. 2758, at 6 (2017); *Retail LLC d/b/a Super Buy Rite*, DAB No. 2660, at 9 (2015).

Analysis

I. *The ALJ did not abuse his discretion in excluding Respondent's proposed exhibits and witness testimony.*

In his APHO, the ALJ instructed the parties that they "must serve all documents electronically by DAB E-File" unless granted a waiver by the ALJ. APHO at 2; *see also* E-Filing Notice for Tobacco Cases, CRD Dkt. Entry 2 ("You are required to use DAB E-File for future submissions unless you are not able to file documents electronically.")

(emphasis removed). The ALJ also instructed Respondent to "file its pre-hearing exchange and serve its pre-hearing exchange on CTP no later than June 19, 2017."[5] APHO at 4 (emphasis removed). The ALJ provided a list of documents that must be included in each party's pre-hearing exchange, including "[a] copy of each proposed exhibit." *Id*. The ALJ further instructed that "[a] party must exchange as a proposed exhibit the complete written direct testimony of any proposed witness… A witness statement must be submitted in the form of a written declaration that is signed by the witness under penalty of perjury for false testimony." *Id*. at 6 (citing 21 C.F.R. §§ 17.25(a), 17.37(b)). The ALJ warned that he "may impose sanctions, including refusing to receive an exhibit or exhibits into evidence, against any party that does not exchange its exhibits in accordance with the requirements of this order." *Id*. at 5-6.

Respondent filed its pre-hearing exchange on July 3, 2017, consisting only of Respondent's pre-hearing brief and a list of proposed exhibits and witnesses. ALJ Decision at 2; CRD Dkt. Entries 9, 10. Respondent's pre-hearing exchange did not include copies of its proposed exhibits, nor did it include written direct testimony from its proposed witnesses. Accordingly, the ALJ issued an OSC which provided Respondent an opportunity to demonstrate that extraordinary circumstances prevented it from filing the proposed exhibits and witness testimony in compliance with the ALJ's APHO and 21 C.F.R. §§ 17.25(a), 17.37(b). ALJ Decision at 3; OSC at 2. In response, Respondent filed its Motion for Leave, in which it stated that it had already provided CTP with its proposed exhibits. Respondent's Motion for Leave did not, however, address its failure to file the proposed exhibits and witness statements as instructed in the ALJ's APHO.

In his order denying Respondent's Motion for Leave, the ALJ wrote that the Motion for Leave failed "to demonstrate that extraordinary circumstances prevented Respondent from complying with the APHO provisions and 21 C.F.R. §§ 17.25(a), 17.37(b)." ODM at 2. The ALJ stated that Respondent "did not exercise due diligence during the pre-hearing exchange process" and "should have reviewed its submission to ensure that copies of proposed exhibits and written declarations of any proposed witness testimony were properly attached." *Id*. at 3 (citing APHO ¶¶ 6, 9-10). The ALJ concluded his analysis by stating:

[5] On May 26, 2017, the ALJ issued an order extending the party's pre-hearing exchange deadlines as requested in a joint motion filed by CTP on May 24, 2017. ALJ Decision at 2 n.2; CRD Dkt. Entry 7. The new deadline for Respondent to file its pre-hearing exchange was July 3, 2017. *Id*.

> Under 21 C.F.R. § 17.35(f), I "may refuse to consider any motion, request, response, brief, or other document that is not filed in a timely fashion or in compliance with the rules of this part." Respondent has not demonstrated that its failure to comply with the pre-hearing exchange rules as provided in the APHO and as required by 21 C.F.R. §§ 17.25(a) and 17.37(b) was due to extraordinary circumstances. Accordingly, Respondent's Motion is hereby denied in its entirety.

ODM at 2-3 (emphasis removed).

Respondent argues that the ALJ abused his discretion in not admitting its proposed exhibits, including the written direct testimony of Mr. Hizam, reiterating its assertion to the ALJ that "[t]he proposed exhibits had already been provided to [CTP], having been served with regard to settlement telephone conference, and on May 22, 2017 with a response to document requests to [Respondent]." Request for Review (RR) at 6; Motion for Leave at 2, ¶ 8.[6] Respondent notes that the proposed exhibits were discussed at the pre-hearing conference on August 3, 2017, more than three months before the hearing, and that the ALJ denied Respondent's Motion for Leave on September 8, 2017, two months before the hearing. Reply at 1-2. Respondent quotes the preamble to the final rule promulgating the procedural regulations found at 21 C.F.R. Part 17 to demonstrate that regulations "are aimed at providing information thirty days prior to the hearing…." Reply at 2 (quoting 60 Fed. Reg. 38,612, 38,619 (July 27, 1995) ("Section 17.25(a) requires that parties exchange written testimony at least 30 days before the hearing. This should eliminate any concern that a party may be unfairly surprised by a witness' testimony presented at a hearing.")). Respondent contends that the ALJ therefore improperly elevated a procedural order that was "more restrictive" than the regulatory requirements on timeliness. *Id*.

We find no abuse of discretion. The governing regulations provide that, "[a]t least 30 days before the hearing, **or by such other time as is specified by the presiding officer** [i.e. the ALJ], the parties shall exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including written testimony." 21 C.F.R § 17.25(a) (emphasis added). Thus, the regulations authorize the ALJ to establish a pre-hearing exchange deadline other than 30 days prior to the hearing. Respondent does not deny that it failed to file its pre-hearing exchange with the CRD by

[6] CTP does not deny that it received outside of the prehearing exchange some of the documents contained in Respondent's proposed exhibits but asserts that that it did not receive copies of the proposed exhibits filed at CRD Dkt. Entries 13i (Contract for Project Greenlight) and 13j (Letter for City Policy) until they were emailed by Respondent's counsel to CTP on July 26, 2017. Response at 16 n.15. CTP also states, "In any event, providing documents in response to a discovery request and/or for purposes of settlement does not excuse a party from complying with the pre-hearing exchange requirements in the regulations and the APHO." *Id.*

the July 3, 2017 deadline established by the ALJ. Moreover, as the ALJ noted, the Hizam Statement "was signed on August 7, 2017, and thus could not have been submitted by Respondent's pre-hearing exchange date of July 3, 2017." ODM at 3. Respondent does not challenge the ALJ's authority to require each party to file its pre-hearing exchange via DAB E-File. Respondent had clear notice of the requirement to file its full exchange, including its proposed exhibits and witness testimony, by the July 3, 2017 deadline by DAB E-File, yet failed to do so. We therefore find no reason to disturb the ALJ's finding that Respondent failed to file its proposed exhibits and witness testimony by the ALJ's deadline in compliance with the ALJ's APHO and the regulations found at 21 C.F.R. §§ 17.25(a) and 17.37(b).

In excluding Respondent's proposed exhibits, the ALJ relied on his sanction authority found at section 17.35(f). The regulations provide that a sanction "shall reasonably relate to the severity and nature of the failure or misconduct." 21 C.F.R. § 17.35(b).[7] Respondent argues that the ALJ's ruling "materially prejudiced" Respondent and made "procedural guidelines… more important than substance." RR at 6; Reply at 2. We disagree. Under the "abuse of discretion" standard applied to ALJ procedural rulings, including imposition of section 17.35 sanctions, "the reviewer may not simply substitute his or her judgment for that of the person exercising discretion." *Vincent Baratta, M.D.*, DAB 1172, at 9 n.5 (1990). Instead, the reviewing body considers only whether the decision-maker has articulated a reasonable basis for the decision under review. *Ranjit*, DAB No. 2758, at 7 (citing *River East Econ. Revitalization Corp.*, DAB No. 2087, at 9 (2007) (in applying an abuse of discretion standard, the Board "will not substitute our judgment" for that of the agency rendering the challenged decision and will "instead ask only whether the agency has articulated a reasonable basis for its decision, not whether it was the only reasonable decision")).

Here, we find that the ALJ articulated a reasonable basis for excluding Respondent's proposed exhibits and witness testimony and that the sanction reasonably related to the severity and nature of Respondent's failure to file by the deadline established by the ALJ. Parties have a responsibility to follow an ALJ's orders. *See Guardian Care Nursing & Rehab. Ctr.*, DAB No. 2260, at 21 (2009) (We have an "overarching responsibility to ensure the efficiency and integrity of proceedings before the [DAB] as a whole, which encompasses a concern that the orders of ALJs not be disregarded [. . .] without consequence."). The ALJ clearly instructed the parties in his APHO which documents each party must file by the pre-hearing exchange deadline set by the ALJ for that party. The APHO set Respondent's pre-hearing exchange deadline at June 19, 2017, but the ALJ later extended that date to July 3, 2017. APHO at 4 (CRD Dkt. Entry 4); Order of May 26, 2017 (CRD Dkt. Entry 7). Moreover, since Respondent filed its prehearing

[7] The regulation at 21 C.F.R. § 17.35(b) reads in full, "[a]ny such sanction, **including, but not limited to**, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct." (emphasis added).

exchange after CTP had filed its exchange, Respondent had an example of what its prehearing exchange should include as well as the express notice given by the ALJ's orders. Despite this, Respondent failed to file its proposed exhibits and witness statements in a timely manner. We find no unfairness in the ALJ's ruling, nor do we find that Respondent was unduly prejudiced. Respondent was afforded a full and fair opportunity to present its case, including the opportunity to submit the testimony of its witnesses and to cross-examine CTP's witness in accordance with the ALJ's APHO. Thus, we conclude that the ALJ did not abuse his discretion in excluding Respondent's proposed exhibits and witness testimony.

II. *The ALJ did not err in restricting the scope of Respondent's cross-examination of CTP's witness.*

Respondent argues that the ALJ abused his discretion in limiting Respondent's cross-examination of CTP's witness (the inspector) to the scope of the witness's written direct testimony. RR at 4-5. We disagree. The regulations grant ALJs broad authority to "[r]egulate the course of the hearing and the conduct of the parties[.]" 21 C.F.R. §§ 17.19(b)(8). Specifically, the regulations provide the following regarding written direct testimony and cross-examination:

> (b) Direct testimony shall be submitted in the form of a written declaration submitted under penalty of perjury. Any such written declaration must be provided to all other . . . parties . . . ;
> (c) The [ALJ] shall exercise reasonable control over the manner and order of questioning witnesses and presenting evidence so as to:
> (1) Make the examination and presentation effective for the ascertainment of the truth;
> (2) Avoid undue consumption of time; and
> (3) Protect witnesses from harassment or undue embarrassment.
>
> (d) The [ALJ] shall permit the parties to conduct such cross-examination as may be required for a full disclosure of the facts.
>
> (e) **At the discretion of the [ALJ]**, a witness may be cross-examined on **relevant** matters without regard to the scope of his or her direct examination. **To the extent permitted by the presiding officer**, a witness may be cross-examined on **relevant** matters with regard to the scope of his or her direct examination. **To the extent permitted by the presiding officer**, cross examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination . . . [.]

21 C.F.R. § 17.37(c)-(e) (emphasis added).

Prior to cross-examination, the ALJ instructed Respondent that "this is not a deposition. The scope of your cross examination should be limited to impeaching the direct testimony of Mr. Bishop as contained in the Center for Tobacco Products Exhibit Number 21." Hearing Transcript at 9. The ALJ also sustained CTP's objection to Respondent's attempt to elicit from the inspector testimony regarding an inspection performed on March 10, 2016 – at a different retail establishment but under the same management – on the ground that the line of questioning was irrelevant to the violations on appeal:

> [Respondent]: . . . Mr. Bishop, you arrived at the Zoom Mini Mart at 6:13 p.m. on March 10, 2016; isn't that right?
> [Inspector Bishop]: Correct.
> [Respondent]: Immediately prior to this you were at a gas station located at 11030 Morang in Detroit; isn't that right?
> [CTP]: I'm going to object, Your Honor, on the grounds that any inspections unrelated to the establishment at issue in this case are irrelevant to the issues in this case.
> [Respondent]: Well, in response it is relevant because this is another facility that's managed by the same management. And the evidence will show that attempt to purchase cigarettes were rejected. This is what we've been arguing from the beginning that there have been dramatic efforts made by the facility, indeed all of the three facilities managed by my client. And instead of this being received it's being rejected and my client's being silenced in an opportunity to provide mitigating circumstances.
> [CTP]: Your Honor . . . again. I'm going to object to counsel's testimony and attempt to get testimony in this case which has been ordered it's not allowed to have. But reiterate my objection that this case is factually about a sale of tobacco products at a facility located at 14545 Plymouth Road in Detroit, Michigan. And any sales or non-sales by respondent at any other locations are irrelevant to whether the sale occurred as alleged in the complaint.
> [ALJ]: Okay. And I sustain that objection at this time.

Hearing Transcript at 10-11, (quoted in ALJ Decision at 8-9). Finally, the ALJ sustained CTP's objection to Respondent's elicitation of testimony regarding prior inspections conducted by Inspector Bishop at Zoom Mini Mart, again on the ground that the line of questioning was irrelevant:

> [Respondent]: Now, Mr. Bishop, you made other attempts to purchase cigarettes at this facility prior to March 10, 2016; isn't that true?
> [CTP]: Excuse me. I'm sorry. I have to object again because Mr. Bishop is here to testify about what happened on March 10th, 2016, as alleged in the complaint. And his observations on that day are what his declaration is about, his sworn declaration. And so anything outside of that would be outside of the scope of his declaration and also irrelevant to the issues in this case.
> [Respondent]: Well, again, it's not irrelevant to the issues. One of the issues that this Court has to determine is whether there are mitigating circumstances. And while the petitioner would like to limit evidence to what they want the tribunal to hear I don't think it stops us from trying to ascertain whether there were other attempts that were rejected.
> [ALJ]: I'm going to have to sustain the objection.

Id. at 11-12.

In his initial decision, the ALJ elaborated on the rationale for his rulings, stating "that [Respondent's] line of questioning is not relevant to the issues before me, which is whether Respondent Zoom Mini Mart, Inc. sold cigarettes or smokeless tobacco to a minor and failed to verify that the cigarette or smokeless tobacco purchaser was of sufficient age, on March 10, 2016, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i)." ALJ Decision at 9. The ALJ's instructions, rulings and rationale for not allowing testimony beyond the scope of the inspector's written direct testimony are fully consistent with the discretion afforded ALJs by the regulations, quoted above. The regulations are explicit that cross-examination must be on "relevant matters." *See also Beatrice State Developmental Center*, DAB No. 2311, at 16 (2010) (quoting *Eilers v. Eilers*, 873 A.2d 185, 191 (Conn. Ap. Ct. 2005) ("[N]othing . . . suggests that a party's right to present evidence is unlimited. To the contrary, . . . the [trial] court reasonably may limit the time allowed for an evidentiary hearing . . . [and] ha[s] the power to control the plaintiff's cross-examination by confining the questions to relevant matters.")) (emphasis added in *Beatrice*). Moreover, the Board has found that "requiring cross-examination to be within the scope of the direct examination is a limitation no more onerous than the rule governing cross-examination in federal courts." *Carrington Place of Muscatine*, DAB No. 2321, at 22 (2010) (quoting Fed. R. Evid. 611(b) ("Cross-examination should be limited to the subject matter of the direct examination and matters affecting the credibility of the witness.")).[8]

[8] Fed. R. Evid. 611(b) was amended on April 26, 2011, effective December 1, 2011, to read "[c]ross-examination should not go beyond the subject matter of the direct examination and matters affecting the witness's credibility." The Advisory Committee Notes for the 2011 amendment state that "[t]he language of Rule 611 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only. There is no intent to change any result in any ruling on evidence admissibility."

We reject Respondent's argument that the ALJ should have allowed the testimony it sought to elicit because it addressed mitigating factors. Regardless of whether the testimony involved liability or mitigating factors, it was still beyond the scope of the inspector's written direct testimony and did not go to the witness's credibility. Moreover, Respondent makes no showing that the inspector, whose testimony was relevant to establishing Respondent's liability for the sale the inspector observed, was even qualified to address mitigation. If Respondent wanted to present its own witness to testify about mitigating factors, it should have submitted written direct testimony for that witness prior to the hearing, within the time frame set by the ALJ. In any event, as we indicated earlier, the ALJ permitted Respondent to brief the issue of mitigating factors in its post-hearing brief and also allowed Respondent to make reference to the case documents in the administrative record although they were not admitted as exhibits. That the ALJ made these allowances notwithstanding Respondent's noncompliance with his orders underscores the lengths to which the ALJ went to assure a fair hearing.

In sum, we find no abuse of discretion or error in the ALJ's rulings.

III. *The ALJ had the authority to impose a NTSO as a remedy for Respondent's repeated violations.*

In Respondent's recitation of the facts, Respondent notes that it argued before the ALJ that CTP "is seeking a NTSO for violations predating the adoption of the NTSO sanction as a penalty." RR at 1 (citing Answer ¶ 12). Respondent also notes that it denied "that an NTSO is appropriate 'for the reason that the regulation providing for [an NTSO] was adopted after all prior CMP violations.'" *Id*. (quoting Answer ¶ 15). Respondent does not address these arguments any further on appeal. In his initial decision, the ALJ noted that Respondent made these arguments in its Answer. ALJ Decision at 6 (citing Answer ¶¶ 12, 15). The ALJ, however, did not address the merits of these arguments apparently because "Respondent, in subsequent briefs, appears to abandon some of the arguments and defenses asserted in its Answer." *Id*. at 6. Moreover, the ALJ found that "Respondent's main argument is that a NTSO is inappropriate because the violations occurred because of a renegade employee." *Id*. at 8 (citing Respondent's Post-Hearing Brief at 2).

To the extent that Respondent raises these arguments on appeal, we find them to be without merit. Congress passed the TCA on June 22, 2009, which amended the Act to authorize the Secretary, *inter alia*, to impose the NTSO remedy on a person who has committed at least 5 repeated tobacco violations at a particular retail outlet within a 36-month period. TCA §§ 103(c), 103(q)(1)(A). While certain amendments that relate to NTSOs became effective with the adoption of the TCA, the remaining amendments

relating to NTSOs (e.g., § 103(q)) became effective upon the issuance of guidance by CTP on April 25, 2011. *See* Guidance for Food and Drug Administration Staff and Tobacco Retailers on Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers; Availability, 76 Fed. Reg. 22,905 (Apr. 25, 2011). Moreover, the regulations prohibiting the sale of tobacco products to a minor and requiring that photographic identification be verified before a tobacco product is sold to purchasers 26 years old or younger were promulgated on March 19, 2010. 75 Fed. Reg. 13,225 (Mar. 19, 2010).

The violations cited in this case were documented between December 31, 2013 (original violations) and March 10, 2016. Complaint ¶ 1 (and the table that follows). Thus, Respondent was on notice that CTP had the authority to impose a NTSO at the time of its first violations. The ALJ found that Respondent committed 6 repeated violations of FDA's tobacco regulations within the 36-month period [from] July 9, 2014, through March 10, 2016." ALJ Decision at 11 (quoting Complaint ¶ 1). Respondent does not challenge these findings on appeal. We therefore conclude that the ALJ had the authority to impose a NTSO on Respondent as a remedy for its repeated violations.

IV. *The ALJ did not err in imposing a NTSO for a duration of 30 calendar days.*

Respondent argues that in finding a 30-day NTSO to be appropriate, the ALJ "improperly failed to consider strong mitigating factors." RR at 7. Respondent cites 21 U.S.C. § 333(f)(5)(B), which 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."[9] *Id*. at 7. The ALJ considered and discussed all of these statutory factors in determining that a 30-day NTSO was appropriate. ALJ Decision at 11-12. Regarding the "nature, circumstances, extent and gravity of the violations," the ALJ found that Respondent committed 3 violations of selling tobacco products to minors, and 3 violations of failing to verify, by means of photographic identification, that the purchasers were 18 years of age or older. *Id*. at 11. The ALJ found that "Respondent's repeated inability to comply with the federal tobacco regulations is serious in nature" and that a "30-day NTSO is a reasonable penalty." *Id*. The ALJ next found that Respondent's "ability to pay" does not

[9] In the "Legal Standards to Be Applied" section of its request for review, Respondent cited an FDA guidance document that refers to these statutory factors and also states that "[i]n determining whether to impose the NTSO or reduce the period of time FDA seeks to impose in the NTSO, FDA will generally consider whether a retailer has taken effective steps to prevent the sale of tobacco products in violation of the minimum age requirements . . ." and then gives examples of such steps. RR at 4 (citing Determination of the Period Covered by a No-Tobacco Sale Order and Compliance with an Order (August 2015), https://www.fda.gov/downloads/TobaccoProducts/Labeling/Rules RegulationsGuidance/UCM460155.pdf). However, in its argument that the ALJ failed to consider the "mitigating factors," Respondent argues only that the ALJ did not correctly apply the statutory factors in 21 U.S.C. § 333(f)(5)(B) referred to in this Guidance.

apply to this case "because the penalty sought is [an] exclusion (NTSO)." *Id*. at 12. The ALJ also found that Respondent did not present any evidence regarding the "effect on [Respondent's] ability to do business," and was not "persuaded that the NTSO would severely hinder [Respondent]'s ability to continue other lawful retail operations during the NTSO period." *Id*. The ALJ looked at the "history of prior violations," noting that "Respondent is a repeated violator of FDA's tobacco regulations" and has "previously twice violated 21 C.F.R. § 1140.14(a), and twice violated… 21 C.F.R. § 1140.14(b)(1)." *Id*. (citing Complaint ¶¶ 1, 6, 9-11). The ALJ found Respondent "fully culpable for six repeated violations of the Act and its implementing regulations" "[b]ased on the Respondent's admission and the preponderance of the evidence. . . ." *Id*.

Respondent does not challenge any of these ALJ findings, and the record does not support Respondent's allegation that the ALJ failed to consider what it alleged were "mitigating factors": posting multiple signs within the store, having an employee training program and a point of sales system that prompts the clerk to ask for a birthdate before tobacco product sales and being involved in various community programs.[10] RR at 2, 7-8. 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." *Id*. at 12-13. The ALJ concluded:

> While I commend Respondent's efforts, I do not find any mitigating factors. Although Respondent has argued bias by CTP, Respondent has failed to provide any evidence of bias against Respondent's establishments. I am not persuaded that Respondent's efforts have been effective for this store.

Id. at 12-13. The ALJ went on to note that this is "the sixth violation within a short period of time for this store" and concluded that, "[b]ecause Respondent is a habitual violator of the FDA tobacco regulations, I find that a 30-day NTSO is necessary." *Id.* at 13. Thus, although Respondent does not agree with the ALJ's conclusion that a 30-day NTSO is appropriate, there clearly is no basis for its assertion that the ALJ did not consider in the process of reaching that conclusion whether the circumstances it alleged constituted "mitigating factors."

Moreover, as the ALJ noted, the 30-day NTSO he found appropriate in this case is consistent with the statute and FDA Guidance given Respondent's six repeated violations of the regulations at 21 C.F.R. Part 1140 within a 36-month period. ALJ Decision at 13 (citing 21 U.S.C. § 333(f)(8) and FDA Civil Money Penalties and No-Tobacco-Sale

[10] Respondent also claims that it fired the clerk who sold tobacco products to the minor. Reply at 4.

Orders For Tobacco Retailers at 5-6). Indeed, Respondent acknowledges that a 30-day NTSO is authorized by the statute and the FDA Guidance for the first NTSO imposed on a retailer. RR at 7. Respondent objects, however, to receiving the same penalty as other retailers "who do not make any effort to stem the tide of teenage smoking," and further objects that "blanketly applying the maximum penalty" is a disincentive for retailers to make the efforts that Respondent has made. Reply at 4-5. Respondent's suggestion that the ALJ "blanketly appl[ied] the maximum penalty" for Respondent's six repeated violations over 36 months has no support in the record or the ALJ Decision. As we have discussed, the ALJ carefully addressed the factors he was required to consider, including what Respondent characterized as "mitigating factors." Nor has Respondent cited any authority for the proposition that an ALJ must compare efforts made by various retailers in determining the appropriate length of a NTSO rather than focusing on the retailer at issue in the case before the ALJ.

Finally, we do not find persuasive Respondent's argument that "in fairness and mercy" the ALJ should have considered the steps Respondent's management allegedly took to prevent the sale of tobacco products to minors as "extenuating or reducing the degree of [the retailer's] moral culpability." *See* Reply at 2-3 (citing a Black's Law Dictionary definition of "Mitigating circumstances" and stating that "[w]hile the factors argued by the Respondent certainly do not support a finding of no culpability, they are clearly mitigating factors"). Even assuming an ALJ might properly find such steps "mitigating" under some circumstances, the ALJ here clearly explained that he declined to do so because the steps were not effective, that is, as Respondent itself acknowledges, the sale of tobacco to a minor in this case occurred notwithstanding Respondent's efforts. Respondent does not explain how the steps its management allegedly took (and which the ALJ appears to have accepted as true at least for purposes of considering whether they would be mitigating here) somehow extenuates or reduces its culpability for that unlawful sale, the sixth within 36 months.

In sum, the ALJ came to his conclusion that a 30-day NTSO was appropriate by following the applicable authority found in the Act and TCA, authority which we are not allowed to ignore or overturn. *See J. Peaceful, L.C. d/b/a Town Market*, DAB No. 2742, at 15 (2016) (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 30 calendar days is appropriate.

Conclusion

For the foregoing reasons, we affirm the ALJ Decision in its entirety and sustain the 30-calendar-day NTSO entered by the ALJ.

/s/
Leslie A. Sussan

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member