Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Sinjil, Inc. d/b/a Sunoco
Docket No. A-18-44
Decision No. 2920
January 14, 2019

REMAND OF ADMINISTRATIVE LAW JUDGE DECISION

The Food and Drug Administration (FDA) Center for Tobacco Products (CTP) appeals the February 14, 2018 initial Decision of an Administrative Law Judge (ALJ). *Sinjil, Inc. d/b/a/ Sunoco*, DAB TB2454 (2018) (ALJ Decision or Decision). The ALJ found that Respondent Sinjil (Respondent) committed within a 36-month period six repeated violations of regulations at 21 C.F.R. Part 1140 issued by the Secretary of Health and Human Services (Secretary) to implement 21 U.S.C. § 387f(d), a provision of section 906 of the Food, Drug, and Cosmetic Act (Act), as amended by the Family Smoking Prevention and Tobacco Control Act (TCA), Pub. L. No. 111-31.

Based on the violations, the ALJ concluded that Respondent was liable for imposition of the No-Tobacco-Sale Order (NTSO) proposed by CTP but reduced the proposed 30-day NTSO period to a two-day period. The ALJ stated as the basis for this reduction his finding that Respondent "was substantially prejudiced by not receiving proper service of the February 13, 2016 Notice of Compliance Check Inspection." ALJ Decision at 25. In addition to imposing an NTSO, although for a shorter period of time than CTP requested, the ALJ imposed a CMP of $7,500, finding a CMP in that amount "appropriate as it is the amount of a CMP for six violations of the regulations less the cost of installing the VeriFone system [which the ALJ regarded as a mitigating factor]." *Id.*

CTP argues that the ALJ erred in reducing the NTSO period by 28 days because the ALJ's premise for the reduction – alleged prejudice due to improper notice – was not legally sound. CTP Appeal Brief (CTP Br.) at 1. CTP further argues that the ALJ abused his discretion in reducing the NTSO period because "[a] two-day NTSO renders the NTSO penalty virtually meaningless, dilutes its deterrent effect, and makes it nearly impossible for CTP to enforce." *Id.* at 2, 22. CTP also argues that the ALJ erred in assessing a $7,500 CMP because the ALJ relied on evidence not properly exchanged or admitted. *Id.* at 1, 17-18. The ALJ Decision does not discuss the ALJ's legal authority for reducing the duration of the NTSO below that proposed by CTP and for imposing a CMP when CTP did not seek that penalty.

Respondent could have appealed the ALJ Decision but did not do so. *See* 21 C.F.R. § 17.47(a), (b) (specifying that either party may appeal the ALJ's initial decision within 30 days after the ALJ issues that decision). Accordingly, the ALJ's determination – that Respondent committed six repeated violations of 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) within a 36-month period, thus establishing a basis for penalties – is final and binding. 21 C.F.R. § 17.45(d). Similarly, the ALJ's imposition of the NTSO penalty itself, apart from the ALJ's reduction of the period the NTSO remains in effect, has not been appealed and, therefore, is final and binding. *Id.* The only issues before the Board, therefore, are the legality of the ALJ's decision to reduce to two days the 30-day NTSO period sought by CTP and the ALJ's decision to impose the additional penalty of a CMP although CTP had sought only an NTSO.

We reverse the ALJ's reduction of the NTSO period. Regardless of whether the ALJ's decision to reduce the NTSO period was based on a proper exercise of authority, (CTP alleges the ALJ abused his discretion – *see* CTP Br. at 21-25), the law does not support the only reason the ALJ gave for that decision. In addition, we decide based on the ALJ's discussion of the regulatory factors he lawfully applied, as well as our own record review, that 30 days is an appropriate period for the NTSO.

We vacate the ALJ's imposition of the CMP and remand with the following instructions. If on remand the ALJ decides to impose a CMP, the ALJ shall issue a decision that:

1) discusses his authority to impose the CMP when CTP did not seek that penalty;

2) explains how the ALJ could lawfully impose a CMP after he concluded that, in cases where CTP seeks a CMP, CTP must prove that Respondent held the tobacco products for sale after shipment in interstate commerce (something CTP appears not to have done in this case, where it did not seek a CMP – *see* ALJ Decision at 18-19). This explanation should include discussion of the effect, if any, of 21 U.S.C. § 379a; and

3) clarifies the evidentiary status of the exhibits that Respondent submitted for the first time with its post-hearing brief, if the ALJ continues to rely on those exhibits. The clarification is needed because the ALJ Decision currently before us does not contain a ruling admitting those exhibits, but only a ruling admitting the exhibits submitted by both parties prior to the hearing (*see* ALJ Decision at 12) and because the ALJ's statement during the hearing that Respondent's post-hearing brief could discuss alleged mitigating circumstances not raised prior to the hearing (Hearing Transcript (Tr.) at 18) did not expressly state that Respondent could also

submit new exhibits.[1]

If, on remand, the ALJ decides not to impose a CMP, he shall issue a decision to that effect and on that issue only, since the ALJ's decision that Respondent is liable for penalties is final and binding and in our decision here, we reinstate the 30-day period of the NTSO for the reasons explained below.

Applicable Law

The Act 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 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B). Congress authorized the 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. 21 U.S.C. § 387f(d). Congress also directed the Secretary to establish the CTP within the FDA to implement the tobacco products provisions of the Act. 21 U.S.C. § 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." 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 required for any person over the age of 26[.]" 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i).[2]

CTP may seek CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products . . . ." 21 U.S.C. § 333(f)(9). CTP also may seek an 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 . . . ." 21 U.S.C. § 333(f)(8). "Repeated violations" are defined as "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet . . . ." TCA, § 103(q)(1)(A) (codified at 21 U.S.C. § 333 note); *see* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December

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[1] In light of our request for clarification, we express no position on CTP's argument that the ALJ abused his discretion in relying on Respondent's post-hearing exhibits, including CTP's suggestion that it did not need to object to admission of these exhibits when they were submitted post-hearing because at the hearing it objected to submission of evidence not submitted prior to the hearing. CTP Br. at 11-13.

[2] 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 to the sections to which we cite without any substantive change. 81 Fed. Reg. 28,974, 29,103 (May 10, 2016); *see* https://federalregister.gov/a/2016-10685.

2016) at 3, 5-6, *available at* https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm.

A person is entitled to a hearing before an ALJ before an NTSO is entered. 21 U.S.C. § 333(f)(8). The Act does not specify the duration of an NTSO but does specify the factors that must be considered in determining the length of an NTSO: "the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , effect on ability to continue to do business[;] any history of prior such violations[;] the degree of culpability[;] and such other matters as justice may require." 21 U.S.C. § 333(f)(5)(B). CTP policy guidelines establish 30 calendar days as the maximum NTSO duration for a first NTSO. *See* Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order, Guidance for Tobacco Retailers at 4 (August 2015), available at http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf.

The CMP hearing regulations permit a retailer to appeal CTP's proposed imposition of 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. 21 C.F.R. § 17.9(a), (c). If the respondent does not file an answer within the prescribed time, the ALJ "shall assume the facts alleged in the complaint to be true" and enter a default judgment "if such facts establish liability under the relevant statute . . . ." 21 C.F.R. § 17.11(a). 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.

Either party dissatisfied with an ALJ decision may appeal that decision (which the regulations refer to as the "initial decision") to the Appellate Division of 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. 21 C.F.R. § 17.47(j).

Case Background[3]

On January 18, 2017, CTP served a Complaint (and cover letter) on Respondent at its place of business, 21435 W. 8 Mile Road, Detroit, MI 48219. ALJ Decision at 2-3; CRD Docket (Dkt.) Entries 1, 2, 3. The Complaint sought to impose an NTSO as a remedy for six repeated violations of FDA's tobacco regulations over a period of 36 months. ALJ Decision at 2; CRD Dkt. Entry 1. The Complaint alleged that on February 13, 2016, an FDA-commissioned inspector inspected Respondent 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 the purchaser was 18 years of age or older by means of photo identification containing a date of birth in violation of 21 C.F.R. § 1140.14(a)(2). ALJ Decision at 3-4; CRD Dkt. Entry 1, ¶ 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 on February 13, 2016 at approximately 12:37 PM" and that "the minor's identification was not verified before the sale, as detailed above, on February 13, 2016, at approximately 12:37 PM." *Id.* CTP filed a copy of the Complaint with the CRD to initiate the proceedings leading to this appeal. ALJ Decision at 2; CRD Dkt. Entry 1.

In addition to charging Respondent with the alleged violations found on the February 13, 2016 inspection, the Complaint noted that the CRD had closed two prior CMP actions involving complaints filed by CTP after Respondent admitted to the allegations in those complaints and paid the agreed upon penalty.[4] ALJ Decision at 5 and n.6; *see also* Complaint ¶¶ 1, 8, 9 and CTP Exs. 4, 6. These prior actions involved two repeated violations of the regulation prohibiting sale of tobacco products to a minor and two repeated violations of failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth. Complaint ¶ 1.

On February 15, 2017, Respondent, through counsel, filed an Answer which neither admitted nor denied the allegations listed in paragraph 5 of the Complaint and stated that Respondent "lack[ed] knowledge or information sufficient to form a belief about the truth of the allegations" in paragraphs 6 and 7 of the Complaint."[5] CRD Dkt. Entry 6. On February 21, 2017, the ALJ issued an Acknowledgment and Pre-hearing Order (APHO) which acknowledged receipt of the Answer and set a schedule for the filing of exhibit

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[3] 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.

[4] The prior violations occurred on March 9, 2013 (sale to a minor and failure to verify age); November 2, 2013 (same) and December 5, 2014 (same), but CTP only sent a warning letter for the violations that occurred on March 9, 2013 and did not count the violations from that date when calculating the total six repeated violations within a 36-month period. *See* Complaint ¶¶ 1 (and the table that follows), 8, 9.

[5] The ALJ stated, "In its Answer and subsequent filings, Respondent could not confirm nor deny the allegations listed in the Complaint." ALJ Decision at 4.

lists and exhibits, witness lists and pre-hearing briefs. CRD Dkt. Entry 7. The APHO specified that the "proceedings are governed by the provisions of regulations at 21 C.F.R. Part 17, which set forth the rights and responsibilities for both parties" and that "[w]ritten direct testimony is governed by 21 C.F.R. §§ 17.25(a), 17.37(b)." APHO at 2, 5.

On June 8, 2017, the ALJ issued an Order Granting In Part and Denying In Part Complainant's Motion for A Protective Order sought in connection with discovery requests made by Respondent. CRD Dkt. Entry 13. On July 14, 2017, CTP filed a prehearing brief, an exhibit and witness list and 23 exhibits marked CTP Exhibits (CTP Ex.) 1-23 that included – as CTP Ex. 21 – a sworn declaration containing the written direct testimony of the FDA-commissioned officer who performed the inspection at Respondent's establishment. CRD Dkt. Entries 18 and 18a-x. On August 4, 2017, Respondent filed its prehearing brief, an exhibit and witness list and seven exhibits marked 1-9, which included – as Respondent Exhibit (R. Ex.) 1 – a sworn declaration containing the written direct testimony of Rafat Iwies, Respondent's owner. CRD Dkt. Entries 23-33.

The ALJ held a hearing by telephone on September 13, 2017. At the hearing, the ALJ admitted, without objection, CTP Exhibits 1-25 and, also without objection, Respondent Exhibits 1-9. ALJ Decision at 9, 11. Respondent cross-examined the FDA inspector. Hearing Transcript (Tr.) at 6-11. CTP declined to cross-examine Mr. Iwies. Tr. at 14, 18. The ALJ noted a comment in Respondent's prehearing brief to the effect that CTP had served the notice of compliance check on a person who was not a registered agent of Respondent and asked Mr. Iwies whether a person named "Eli" had worked for Respondent at the time. Tr. at 15-17. Mr. Iwies replied "No." *Id.* at 16-17. The ALJ asked if there was "anything that's not contained in the [Iwies] declaration that the Court should consider[,]" and indicated he would "consider the argument." Tr. at 14. Respondent's counsel responded as follows:

> The only thing, obviously, the declaration lays out what has been – what the owner has done so far in terms of minimizing. The only other thing that I wanted to ask is if this penalty is enacted, or if you decide on a no sale tobacco, I wanted Mr. Iwies to just tell you in his own words what it would do to his business, if you would allow it, your honor.

Tr. at 14-15. CTP's counsel then stated, "I would object to that. As Your Honor mentioned about the regulations, not allowing direct testimony beyond that submitted in the written declaration." Tr. at 15. The ALJ responded that "the way to handle that" was to allow Respondent to address mitigation in his post-hearing brief. Tr. at 15, 18. The ALJ further stated that if Respondent's argument for mitigation in that brief went beyond Mr. Iwies' declaration, he would allow CTP to file a supplement to its post-hearing brief "to address any issues that may concern you." *Id.*

The parties filed post-hearing briefs on December 8, 2017. Respondent's post-hearing brief did not deny the sale of tobacco products to a minor or the failure to check the minor's identification.[6] Instead, Respondent "respectfully request[ed] [the ALJ] to consider its efforts to mitigate outstanding issues concerning the sale of tobacco products at its retail location," discussing the July 2016 purchase and installation of a VeriFone system costing "approximately $3,500.00 . . . ." R. Post-hrg. Br. at unnumbered page 2. (The purchase and installation was approximately five months after the February 13, 2016 inspection that led to the CTP action before us.) Respondent stated, "In the event [the ALJ] is inclined to grant a No Tobacco Sale Order, Respondent respectfully requests that [the ALJ] consider a No Tobacco Sale Order of minimal duration in addition to an appropriate [CMP], in lieu of the requested 30-Day No Tobacco Sale Order." *Id.*, at unnumbered page 3. Respondent submitted with its post-hearing brief seven "exhibits" that included six photographs of the VeriFone system and a "Post-Hearing Declaration of Rafat Iwies." CRD Dkt. Entries 40 and 40a-g. CTP did not ask to file a reply to Respondent's post-hearing brief or an objection to the new "exhibits." The ALJ did not include these new exhibits in his ruling admitting exhibits but relied on them to modify the Penalty along the lines requested in Respondent's post-hearing brief.

Standard of review

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

Analysis

Because Respondent did not appeal the ALJ Decision, the ALJ's determination that Respondent was liable for the unlawful acts to which it admitted (six repeated violations of sections 1140.14(a)(1) and 1140.14(a)(2)(i) within a 36-month period) is final and binding. *See* 21 C.F.R. § 17.45(d). For the same reason, the ALJ's imposition of the NTSO as a penalty – as distinct from the ALJ's determination of the NTSO's duration – is final and binding. *Id.* That leaves the following as the only issues for our review: 1) whether the ALJ erred in reducing the duration of the NTSO and 2) whether the ALJ erred or abused his discretion in imposing a CMP or in determining the $7,500 amount of the CMP.

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[6] Respondent argued in its Post-hearing brief that as a matter of law, it could not be held liable for the admitted acts because CTP had not provided evidence that the tobacco product at issue "was actually involved in interstate commerce . . . ." Respondent's Post-hearing Brief (R. Post-hrg. Br.) at unnumbered page 2. The ALJ concluded that such proof was required only in cases where CTP sought to impose a CMP. ALJ Decision at 18-19.

A. The ALJ erred in reducing the NTSO period sought by CTP because the "mitigating factor" the ALJ cited as the basis for that reduction is legally insupportable, and a 30-day NTSO is supported by the applicable regulatory factors and the record.

1. The ALJ based his reduction of the NTSO period solely on his acceptance of Respondent's argument that Respondent was prejudiced by improper service of the Notice of Compliance Check Inspection (NCCI) and that this was a mitigating factor warranting the reduction.

Having found Respondent liable, the ALJ proceeded to determine an appropriate penalty. After correctly concluding that "NTSOs are authorized at 21 U.S.C. § 333(f)(8)[,]" the ALJ stated the factors he must consider under 21 U.S.C. § 333(f)(5)(B)).

> When determining the appropriate penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require."

ALJ Decision at 20, 21-22 (citation omitted). We excerpt the ALJ's findings regarding those factors as follows:

- Nature, circumstances, extent and gravity of the violations: "The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the penalty should be set accordingly."
- Effect of the NTSO on Respondent's business: "[N]one of the data presented by Respondent has shown what portions of its profits are derived from the sale of tobacco products."
- History of prior violations: "Respondent's history of noncompliance demonstrates its continued inability to comply with the federal tobacco regulations."
- Degree of culpability: "I hold [Respondent] fully culpable for six (6) repeated violations of the Act and its implementing regulations."

ALJ Decision at 22-23. The ALJ then went on to consider "Additional Mitigating Factors" alleged by Respondent – improper service of the NCCI and post-inspection purchase of a VeriFone system. *Id*. at 23-24. The ALJ noted that Respondent bore the burden of proof on the alleged mitigating factors, *id*. (citing 21 C.F.R. § 17.33), and concluded that Respondent had met its burden to prove the alleged mitigating factors. With respect to service of the NCCI, the ALJ concluded, "In this instance, I find and conclude Complainant's ineffective service of process prejudiced Respondent's ability to

defend the claim." ALJ Decision at 24. With respect to the VeriFone system, the ALJ referred to Respondent's post-hearing brief and concluded, "Respondent has provided unrebutted evidence of a new VeriFone system installed on its register that will help ensure accuracy in checking identification for the sale of tobacco products." *Id*. at 23 (citing R. Post-hrg. Br. at 2-3).

CTP argues that the ALJ erred in concluding that it had failed to properly serve the NCCI, arguing, in main, that it had no legal obligation to serve that document. CTP Br. at 14-17. CTP further argues that the ALJ could not apply the VeriFone system as a mitigating factor because doing so required the ALJ to rely on evidence submitted only after the hearing which, CMS asserts, the ALJ could not properly do. For purposes of determining whether the ALJ erred in reducing the NTSO period, we need only address the ALJ's finding that Respondent was prejudiced by improper service of the NCCI. We need not address the VeriFone argument with respect to that issue because, contrary to what CTP appears to believe, the ALJ did not cite the VeriFone system as a basis for that reduction.[7] The ALJ relied only on the alleged improper service of the NCCI for that determination, stating, "I find a two (2) day NTSO appropriate as Respondent was substantially prejudiced by not receiving proper service of the February 13, [NCCI]." *Id*. at 25. The ALJ cited the VeriFone system only in determining to impose the additional penalty of a CMP and the amount of the CMP, stating: "I find that the CMP is appropriate as it is the amount of a CMP for six violations of the regulations less the cost of installing the VeriFone system." *Id.*

2. *The ALJ erred in accepting Respondent's argument for reducing the NTSO period because there is no legal requirement that CTP serve an NCCI, and we decide that a 30-day period is appropriate based on the regulatory factors lawfully applied by the ALJ and the record relating to those factors.*

The ALJ accepted Respondent's argument regarding the alleged improper service of the NCCI and resulting prejudice without citing any legal authority to support his conclusion that CTP had not properly served the NCCI. ALJ Decision at 25. Earlier in the Decision, when concluding that Respondent was liable for the admitted unlawful sales of tobacco to minors, the ALJ concluded that Respondent waived use of the same alleged improper service argument as a defense when it answered the Complaint without challenging service or jurisdiction.[8] *Id*. at 18. In discussing that conclusion, the ALJ cited the service requirements in 21 C.F.R. § 17.7. However, as CTP notes, section 17.7 applies, as the

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[7] As we conclude later, we also need not address this argument with respect to the CMP issue, since we are vacating the CMP and remanding for further proceedings on that issue.

[8] Respondent answered that it was "unable to confirm or deny" the allegations of liability due to the alleged lack of proper notice, but, as the ALJ properly concluded, "*allegations [of liability] not specifically denied in the answer are deemed admitted*." ALJ Decision at 18 (citing 21 C.F.R. § 17.9(b)(1) (emphasis in ALJ Decision) (internal quotation mark omitted).

regulation's title states, to "Service of complaint[s,]" and the NCCI was not a complaint. Rather, it was a notice that, among other things, informed Respondent that FDA conducted the February 13, 2016 inspection, that the inspector "reported that a minor was able to enter [the] establishment and purchase a regulated tobacco product[,]" that CTP would review the inspection evidence and, that if CTP found violations, the "establishment will receive: a Warning Letter *or* a notice that FDA is seeking a fine."[9] CTP Ex. 12 (emphasis added). Respondent subsequently received "a notice that FDA is seeking a fine," that is, the Complaint at issue here, and it is undisputed that CTP served the Complaint in compliance with section 17.7. *See* CRD Dkt. Entry 3 (UPS Delivery Notification receipt).

Not only does section 17.7 not apply to the NCCI, there is no support in the statute for the ALJ's finding of improper notice. The applicable statutory provisions require only "timely and effective notice by certified or registered mail or personal delivery to the retailer of each alleged violation at a particular retail outlet prior to conducting a followup compliance check," and "notice to the retailer of all previous violations at that outlet" prior to charging a person with a violation. 21 U.S.C. § 333 Note (TCA § 103(q)(1)(B), (D)). Neither requirement applies to the NCCI, and it is undisputed that CTP complied with both provisions in the present case. With respect to the first, the Board has held that it "may reasonably be read as requiring only that, having found the retailer to be committing acts in violation of law, CTP must so inform the retailer before returning to the establishment to conduct another inspection . . . ." *Orton Motor Co., d/b/a Orton's Bagley*, DAB No. 2717, at 19 (2016), *aff'd*, *Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs.*, 884 F.3d 1205 (D.C. Cir. 2018). Here (as in *Orton*), CTP complied with this regulation by sending Respondent a June 27, 2013 Warning Letter notifying it of the illegal sale of tobacco to a minor and failure to check the purchaser's identification found during the initial inspection on March 9, 2013, and advising that failure to correct the violations (as determined by follow-up inspections) "may lead to federal enforcement actions, including monetary penalties." CTP Ex. 1. Respondent has not raised any issue about the service of the Warning Letter in this case and if there were any issues about that document in prior cases, they were mooted by the default judgments. The second requirement also is not at issue here since there is no dispute that the Complaint initiating this enforcement action seeking penalties was properly served, and that the Complaint gave notice of all previous violations at Respondent's establishment, violations for which CTP took prior enforcement actions successfully seeking CMPs. *Cf. Orton*, 884 F.3d at 1215 ("The TCA requires [notice and hearing] procedures only for the assessment of civil money penalties . . . .").

[9] CTP describes the NCCI as an "informal notice of violations sent to Respondent as a courtesy after the violations occurred and which CTP has no legal obligation to send." CTP Br. at 15. We need not address whether the description "informal notice of violations sent to Respondent as a courtesy" is accurate since we agree no statute or regulation requires CTP to send an NCCI at all, much less effect service.

Respondent points to statements in CTP guidance documents which, Respondent says, show that CTP has imposed on itself an obligation to send an NCCI and "provide timely and effective notice." Response to Notice of Appeal at 8-9. The guidance documents, however, provide guidance to the regulated entities, explaining CTP's enforcement practices. Although ALJs and the Board may evaluate whether discretionary policy choices expressed in guidance documents are consistent with the statutes, *Orton*, DAB No. 2717, at 20, the guidance documents do not have the legal force and effect of the statutes and regulations that CTP must follow. Moreover, the guidance provisions cited by Respondent here are wholly consistent with the statutes. The first guidance cited by Respondent says, "Shortly after any inspection in which a retailer sells tobacco products to a minor, CTP issues a [NCCI] informing the retailer of the sale and explaining that CTP will make a final determination regarding whether there has been a violation of federal law." Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions, Guidance for Industry at 12 (December 2016 revision).[10] That guidance merely states CTP's discretionary choice to issue an NCCI; it does not say CTP is required to issue an NCCI and does not address at all how CTP must send such an issuance to retailers. *See id.* The second guidance cited by Respondent merely recites the requirements at sections 103(q)(1)(B) and (D) of the TCA that, as discussed above, do not relate to the NCCI and, even if the guidance applied, it does not establish any requisites for what constitutes "timely and effective notice." *See* Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Guidance for Industry at 4 (December 2016 revision).[11] In addition, the guidance specifically states, "This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public." *Id.* at 1.

In summary, the ALJ erred as a matter of law in concluding that CTP did not properly serve the NCCI and thereby prejudiced Respondent.[12] In addition, but for the ALJ's applying a "mitigating factor" that we find legally insupportable, the ALJ's discussion of the regulatory factors provides no apparent basis for his reduction of the NTSO period. Based on the ALJ's discussion of the regulatory factors he lawfully applied (nature of the violations, Petitioner's ability to pay and effect on his business, the history of Petitioner's prior violations and Petitioner's culpability), as well as our own review of the record relating to those factors, we decide that 30 days is an appropriate period for the NTSO.

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[10] This guidance can be found on the internet at https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/UCM447310.pdf.

[11] This guidance can be found on the internet at https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/UCM252955.pdf.

[12] Since we reverse this conclusion on legal grounds, we need not discuss whether the record provides any factual support for the alleged improper service or alleged prejudice.

B. Because the ALJ Decision does not sufficiently explain the ALJ's authority and basis for imposing a CMP that CTP did not seek and also contains an unexplained inconsistency in legal analysis regarding the CMP, we vacate the CMP and remand for further proceedings and a new decision on that issue alone.

As previously noted, the ALJ stated, "Based on the foregoing reasoning, . . . a two (2) day NTSO and a $7,500 CMP is appropriate under 21 U.S.C. § 333(f)(8)."[13] ALJ Decision at 24-25. With respect to the CMP, the ALJ stated, "I find that the CMP is appropriate as it is the amount of a CMP for six violations of the regulations less the cost of installing the VeriFone system."[14] *Id*. at 25. Section 333(f)(8) is the only authority the ALJ cited for his decision to impose the CMP, a penalty not sought by CTP. The ALJ is correct that section 333(f)(8) authorizes the Secretary to impose a CMP in addition to an NTSO in the event of repeated violations:

> If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 387f(d) of this title at a particular retail outlet then the Secretary may impose a [NTSO] on that person prohibiting the sale of tobacco products in that outlet. A [NTSO] may be imposed with a civil penalty under paragraph (1).

The statute, however, does not specifically address whether an ALJ is authorized to impose the additional remedy of a CMP where, as here, CTP seeks to impose only an NTSO for repeated violations.[15] The ALJ did not explain why that statute authorized his action to impose the unsought CMP; nor did he cite or discuss any other authority for his action. In addition, there is an unexplained inconsistency between the ALJ's legal analysis earlier in his Decision that when CTP seeks a CMP, it needs to prove that the tobacco product was sold after shipment in interstate commerce and the ALJ's imposition of a CMP without finding that CTP made this proof.

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[13] We take "the foregoing reasoning" to mean the ALJ's discussion of the statutory factors in 21 U.S.C. § 333(f)(5)(B) that an ALJ is required to consider when determining an appropriate penalty as well as the mitigating factors for which he found Respondent had met its burden of proof under 21 C.F.R. § 17.33(c). *See* ALJ Decision at 20-24.

[14] In reducing the NTSO to two days and imposing a CMP that took into account the VeriFone system installed after the hearing, the ALJ effectively provided the relief sought by Respondent in its post-hearing brief. *See* ALJ Decision at 21 ("Respondent objects to the thirty (30) day NTSO. Respondent requests that the NTSO be denied, or that I consider an NTSO of minimal duration in addition to an appropriate CMP.") While an ALJ, of course, may be persuaded by a party's position, it is incumbent on the ALJ to address the legal authority on which the ALJ relies for adopting that position, especially when the issue, as here, is one of first impression.

[15] The statute also does not address whether an ALJ is authorized to impose an NTSO if CTP seeks only a CMP for repeated violations. However, this case does not present that issue so we need not address it.

Remand is necessary for the ALJ to address these legal issues. We note that the first issue – ALJ authority to impose the CMP when CTP did not seek that penalty – is one of first impression before the Board.[16] As a general rule, it is prudent that such issues be addressed in the first instance in the ALJ decision.[17] We take no position on this issue at this time but find it necessary to have the ALJ discuss his authority rather than simply assuming it (as appears to be the case), especially in light of the Board's previously expressed concern about recognizing the proper spheres of administrators and adjudicators in the enforcement process for the prohibition against tobacco sales to minors. *See Orton,* DAB No. 2717, at 25 (discussing the respective provinces of the enforcement agency and the adjudicator and concluding that the ALJ "lack[ed] authority and improperly conflate[ed] the role of adjudicator with that of an enforcement agency" when he undertook to issue his own Warning Letter and reduced the CMP sought by CTP to zero). We recognize that issuing a warning letter and imposing a remedy not sought by CTP may raise different issues, and our citation to *Orton* should not be read as suggesting any conclusion by the Board on the latter issue or any conclusion as to whether or how *Orton* might influence that decision. However, that case helps explain why we find it necessary for the ALJ to explain his legal rationale for deciding that it was within his province to impose the CMP in this case.

Remand on the CMP issue is also necessary because the ALJ imposed the CMP without requiring CTP to prove that Petitioner held and sold the cigarettes in question to the minor after they had been shipped in interstate commerce, even though the ALJ had concluded earlier in his Decision that CTP would be required to put on such proof if it sought to impose a CMP, which it had not done in this case. ALJ Decision at 18-19. We take no position at this time as to whether the ALJ correctly stated what the law requires when he concluded that such proof was necessary before a CMP could be imposed. We note that CTP, appearing to share the ALJ's view, stated in its post-hearing brief that "CTP must prove that the tobacco products traveled in interstate commerce in its civil money penalty cases . . . ." (CTP Post-hrg. Br. at 4 n.3).[18] However, neither the parties

[16] The ALJ whose decision we are reviewing here imposed an unsought CMP (and reduced the NTSO period sought by CTP) in another case, *Mike Petroleum Inc. d/b/a Plaza BP*, DAB TB2306 (December 18, 2017), but that decision was not appealed to the Board. The ALJ did not discuss his authority for imposing the unsought CMP in that case either.

[17] We also note that although Petitioner requested in its post-hearing brief denial of the NTSO or reduction of the NTSO to a minimal period along with imposition of a CMP, the ALJ himself did not notify the parties that he was considering making such changes to the penalty sought by CTP; nor did the ALJ solicit briefing on the issue from the parties.

[18] CTP, like the ALJ, contrasted this with cases where CTP seeks only an NTSO. *Id.* (stating that no such proof is required when CTP seeks only an NTSO); *see also* CTP Reply at 9 (agreeing with the ALJ's conclusion (ALJ Decision at 18-19) that when CTP seeks only an NTSO, nothing in the statute requires CTP to prove that the tobacco products in question were held and sold after traveling in interstate commerce, that CTP need only prove that the retailer committed five or more repeated violations of the regulations at 21 C.F.R. § 1140).

nor the ALJ addressed the effect, if any, that the "Presumption of existence of jurisdiction" in 21 U.S.C. § 379a might have on that issue. The statute states as follows:

> In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

See also U.S. v. Blue Ribbon Smoked Fish, Inc., 179 F. Supp. 2d 30 (E.D. N.Y 2001); *U.S. v. Torigian Labs., Inc*., 577 F. Supp. 1514 (E.D. N.Y. 1984) (each applying the presumption but also noting that FDA put on proof of the interstate commerce connection). If the ALJ on remand, decides to reimpose the now vacated CMP, he should discuss his authority to impose a CMP when CTP does not seek that penalty and explain why he does not find imposition of that penalty inconsistent with his conclusion regarding the need for proof of an interstate commerce connection. The latter discussion should address the effect, if any, of 21 U.S.C. § 379a.

Finally, if the ALJ decides to reimpose the CMP, and if he continues to rely on Petitioner's exhibits regarding installation of a VeriFone system as a basis for the CMP, the ALJ must clarify the evidentiary status of those exhibits because they were submitted post-hearing, and the ALJ Decision does not indicate that the ALJ formally admitted them to the record. *See* ALJ Decision at 12 (admitting only CTP Exs. 1 through 23 and R. Exs. 1 through 9).

Conclusion

We conclude that the ALJ's determination that Respondent is liable for penalties based on six repeated violations of 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) and his decision to impose an NTSO (but not his determination of the duration) are final and binding. For the reasons stated above, we reverse the ALJ's reduction of the 30-day NTSO period sought by CTP and decide that a 30-day period is appropriate for the NTSO. We vacate the CMP imposed by the ALJ and remand with the following instructions. If the ALJ again determines to impose a CMP, he shall do so in a new decision on that issue alone that is consistent with our decision and contains:
1) discussion of his authority to impose a CMP when CTP did not seek that penalty; 2) an explanation, as to why his imposing a CMP is not inconsistent with his analysis that CTP must prove that the unlawfully sold tobacco product had been shipped in interstate commerce (which it apparently did not do here) when it seeks to impose a CMP; and 3) clarification of the evidentiary status of Respondent's VeriFone exhibits, assuming the ALJ continues to rely on those exhibits. As indicated above, the ALJ's discussion of the

interstate commerce issue should include discussion of 21 U.S.C. § 379a. On remand, the ALJ may conduct such additional proceedings as he deems necessary and consistent with our decision. If the ALJ decides not to impose a CMP, he shall issue a decision to that effect and on that issue only.

/s/
Christopher S. Randolph

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member