

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

Kuma H. Mamie d/b/a 7-Eleven Store 22921A  
Docket No. A-18-29  
Decision No. 2877  
June 25, 2018

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

Kuma H. Mamie d/b/a 7-Eleven Store 22921A (7-Eleven Store 22921A or Respondent) appeals the December 27, 2017 initial decision of an Administrative Law Judge (ALJ) imposing a 30-calendar-day No-Tobacco-Sale Order (NTSO) against Respondent for five 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. *Kuma H. Mamie d/b/a 7-Eleven Store 22921A*, DAB TB2335 (2017) (ALJ Decision). The ALJ issued her decision following a hearing on an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) in which CTP alleged that during an FDA inspection on January 30, 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 on December 13, 2012, November 19, 2013, and October 2, 2014, and failed to verify the age of a purchaser via photographic identification on December 13, 2012 and October 2, 2014.

The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for imposition of an NTSO. For the reasons explained below, we affirm the ALJ Decision.

**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 387f(d) of the Act. *Id.* § 387c(a)(7)(B). Congress authorized the Secretary of Health & Human Services (Secretary) to adopt regulations that impose “restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and

the advertising and promotion of, the tobacco product” as appropriate to protect public health. *Id.* § 387f(d). Congress also directed the Secretary to establish CTP within the FDA to implement the tobacco products provisions of the Act. *Id.* § 387a(e). The regulations adopted by the Secretary 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.* § 1140.14(a)(2)(i).<sup>1</sup>

CTP may 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 impose 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 . . . .” *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. . . .” Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 § 103(q)(1)(a) (cited in 21 U.S.C. § 333 note); *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 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, 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 policy guidelines establish 30 calendar days as the maximum NTSO duration for an establishment’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 an 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

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<sup>1</sup> 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 re-codified to the sections to which we cite without any substantive change. 81 FR 28,973, 28,974, 29,103; *see* <https://federalregister.gov/a/2016-10685>.

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<sup>2</sup>**

### 1. The Complaint and the Hearing

On October 19, 2016, CTP served a Complaint (dated October 18, 2016) on 7-Eleven Store 22921A at its place of business, 8101 Fenton Street, Silver Spring, Maryland 20910. ALJ Decision at 2; Complaint; CRD Docket (Dkt.) at 2. The Complaint sought to impose an NTSO as a remedy for five repeated violations of FDA’s tobacco regulations over a period of 36 months. ALJ Decision at 2; Complaint at 1. The Complaint alleged that on January 30, 2016, an FDA-commissioned inspector inspected 7-Eleven Store 22921A 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 photo identification containing a date of birth in violation of 21 C.F.R. § 1140.14(a)(2)(i). ALJ Decision at 1-2; Complaint ¶ 10. 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 cigarettes on January 30, 2016 at approximately 8:27 AM” and that “the minor’s identification was not verified before the sale, as detailed above, on January 30, 2016, at approximately 8:27 AM.” *Id.* CTP filed a copy of the Complaint with the CRD to initiate the proceedings leading to this appeal. ALJ Decision at 2.

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<sup>2</sup> The factual findings stated here are taken from the ALJ Decision and the administrative record. We make no new findings of fact, and the facts stated are undisputed unless we indicate otherwise.

In addition to charging Respondent with the alleged violations found during the January 30, 2016 inspection, the Complaint noted that the CRD had closed three prior CMP actions involving complaints filed by CTP.<sup>3</sup> ALJ Decision at 2 (citing Complaint ¶¶ 1, 10, 13-15). The first action was decided by default. Complaint ¶ 15. Respondent settled the second action and paid the agreed upon penalty. *Id.* ¶ 14. In the third action, Respondent admitted liability and was ordered by the ALJ to pay a reduced penalty amount. *Id.* ¶ 13. These prior actions involved one original violation and two repeated violations of the regulation prohibiting sale of tobacco products to a minor, and one original violation and one repeated violation for failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth. *Id.*

On November 17, 2016, Respondent filed an Answer denying the allegations in the Complaint. ALJ Decision at 2; CRD Dkt. Entry 5. On December 9, 2016, the ALJ issued an Acknowledgment and Pre-hearing Order which acknowledged receipt of the Answer and established procedural deadlines. CRD Dkt. Entry 7. Respondent filed a prehearing brief on January 12, 2017, but did not file exhibits or a list of proposed witnesses as instructed by the Pre-hearing Order. CRD Dkt. Entry 9. On March 30, 2017, CTP filed a prehearing brief, an exhibit and witness list and 28 exhibits numbered 1-28. ALJ Decision at 2; CRD Dkt. Entries 16 and 16a-z, a1-a3.

The ALJ held a hearing on July 13, 2017, at which she admitted CTP's exhibits and heard cross-examination testimony from the only CTP witness whom Respondent asked to cross-examine, the FDA inspector who conducted the January 30, 2016 inspection at Respondent's establishment. ALJ Decision at 3. Respondent filed a post-hearing brief dated October 3, 2017. CRD Dkt. Entry 25 (Post-Hearing Brief). In the brief, Respondent recounted his memory of the alleged January 30, 2016 violations, writing in relevant part:

I myself was in [the] store standing by the register when the inspector showed-up in the store. I greeted her and she asked me if I would let her use the bathroom. I said to her that this is the bathroom and even asked her is there any problem? In which she replied, not at all. After a few minutes she went outside [the] store and slightly turned left and took [a] picture. I have never sold any tobacco products to [this] minor because I have [a] clear memory of the time before, during[,] and after her arrival on this particular date.

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<sup>3</sup> The prior violations occurred on December 13, 2012 (sale to a minor and failure to verify age), November 19, 2013 (sale to a minor), and October 2, 2014 (sale to a minor and failure to verify age), but CTP did not count the violations that occurred on December 13, 2012 when calculating the total of five repeated violations within a 36-month period. *See* Complaint ¶¶ 1 (and the table that follows) and 15.

Post-Hearing Brief at 3-4. Respondent also argued that the imposition of an NTSO would put his “contract with 7-Eleven in jeopardy” and that his store “is losing 150 customers on average per day” and “13% of daily sales” due to increased competition from other stores. *Id.* at 4-5.

## 2. The ALJ Decision

On December 27, 2017, the ALJ issued her 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 January 30, 2016 by selling tobacco products to a minor and failing to verify that the tobacco product purchaser was of sufficient age. ALJ Decision at 7. In reaching her conclusion, the ALJ relied on the testimony of the inspector who documented the violations, finding that the inspector “testified credibly and comprehensively about her observations during the January 30, 2016, inspection at which she observed Respondent selling tobacco products to” the minor. *Id.* at 6. The ALJ found that Respondent failed to submit “evidence sufficient to rebut CTP’s allegations,” and that, “[w]hile Respondent successfully established that he was working the register at the time of the alleged violations, his memory of what occurred [on January 30, 2016] is not supported by any other evidence.” *Id.* at 5.<sup>4</sup> The ALJ noted that “Respondent’s claim that he was working the register on the date and time of the alleged violations supports [the inspector’s] Narrative Report [which] describes the employee as an adult male with black/dark brown hair and a mustache.” ALJ Decision at 5 (citing CTP Ex. 20, ¶ 16).

The ALJ next determined the duration of the NTSO, taking into account the factors listed in 21 U.S.C. § 333(f)(5)(B). The ALJ noted that “Respondent committed a total of five repeated violations of FDA tobacco regulations within a . . . 36 month period” and concluded that “Respondent’s repeated inability to comply with federal tobacco regulations raises a serious concern for the wellbeing of minors.” ALJ Decision at 7. The ALJ found that “Respondent submitted no evidence in support” of its assertion that an NTSO would result in a material breach of its franchise contract with 7-Eleven, and:

[b]ased on the available evidence, [the ALJ] cannot conclude that a 30-day NTSO would severely hinder Respondent’s ability to continue other lawful retail operations during the NTSO period. Moreover, “the need to protect

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<sup>4</sup> The ALJ states in her Decision that she did not consider the testimony Respondent attempted to introduce at the hearing “as to his personal recollection of the events on the date and time of the alleged violations” because Respondent did not submit “written direct testimony” (in the form of a declaration under oath) as required by her Prehearing Order. ALJ Decision at 6 (citing APHO (Prehearing Order) at ¶¶ 9-10, 21 C.F.R. §§ 17.25(a), 17.37(b)); see also Hearing Transcript 19-21 (advising Respondent that she could not treat his statements at the hearing as testimony).

the [minors] outweighs the adverse effects that an NTSO may have on an individual retailer's business, especially in light of the fact that imposition of this remedy is reserved only for those retailers who demonstrate indifference to the requirements of law." Kat Party Store, Inc., d/b/a Mr. Grocer Liquor Store, CRD No. T-16-1684, at 3-4 (2016).

*Id.* at 8. The ALJ documented Respondent's prior violations, and found that "Respondent has an extensive history dealing with CTP complaints, is amply familiar with the process, but is unrepentant." *Id.* The ALJ also found that Respondent is "fully culpable for all five repeated violations." *Id.* at 9. Finally, the ALJ did "not find any mitigating factors," noting that any training programs that Respondent requires its sales associates to pass to prevent the illegal sale of tobacco products to minors "have proven ineffective . . ." *Id.* Based on these analyses, the ALJ "impose[d] an [NTSO] against Respondent . . . for a period of 30 consecutive calendar days." *Id.*

### **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**

For the following reasons, we conclude that the ALJ's findings are supported by substantial evidence on the whole record and free of legal error.

On appeal, Respondent argues that there was "not enough evidence to support" the ALJ's conclusion that the record supported CTP's allegations that an employee sold a package of cigarettes to a minor without checking photo identification on January 30, 2016. Request for Review (RR) at 2. On the contrary, we conclude that substantial evidence in the record supports the ALJ's conclusion. The ALJ relied importantly on the inspector's testimony that she witnessed the alleged violations. Having reviewed the inspector's testimony, we find no basis to disturb the ALJ's finding that she "testified credibly and comprehensively about her observations" or the ALJ's conclusion that "the violations occurred as [the inspector] reported." ALJ Decision at 6 (citing Hearing Transcript at 21-22, 45; CTP Ex. 27). Respondent faults the ALJ for allegedly "bas[ing] her decision solely on the testimony of [the] inspector." RR at 4. However, the ALJ did not rely solely on that testimony. She also cited the inspector's narrative report, completed on the day of the inspection, which is consistent with her testimony. ALJ Decision at 6 (citing CTP Ex. 20).

Respondent cites no evidence of record disputing the ALJ's findings, and we find no reason to disturb those findings. Respondent argues here, as it did before the ALJ, that the inspector did not provide the name of the employee who sold cigarettes to a minor, or a receipt showing proof of purchase. RR at 3-4. The ALJ found no requirement that CTP provide a receipt for the minor's purchase. ALJ Decision at 6. The ALJ also found, and the record supports this, that though the inspector did not provide the name of the employee who sold cigarettes to the minor, the inspector's description of the employee – an adult male with black/dark brown hair and a mustache (CTP Ex. 20, at 2) – is supported by Respondent's admission that he was working the register on the date and time of the alleged violations. ALJ Decision at 5; Post-Hearing Brief at 4. We agree with the ALJ that there is nothing in the Act or regulations – and Respondent cites no contrary authority – requiring CTP to provide a receipt showing proof of purchase. Likewise, we concur in the ALJ's finding that the lack of a receipt of purchase is “outweighed by the highly credible testimony of [the inspector].” ALJ Decision at 6; *see also J. Peaceful, L.C. d/b/a Town Market*, DAB No. 2742, at 9 (2016) (“Absent any actual evidence that the inspector testified falsely . . . , the ALJ could reasonably credit his testimony and the physical evidence as showing that Respondent sold cigarettes to the minor...”). Nor does the Act or regulations require CTP to name the employee who sold cigarettes to a minor. In short, the ALJ properly relied on the testimony of the inspector, and her contemporaneous reports, as supporting CTP's allegations.

Respondent also argues that a 30-day NTSO is “unreasonable” and that the ALJ “hardly consider[ed] the policy guidelines that establish maximum NTSO duration.” RR at 4. Respondent claims that the ALJ did not weigh its “testimony” that an NTSO “is considered a material breach of [its] franchise contract with 7-Eleven” and that “he would lose ‘150 customers on average per day’ and ‘13% of daily sales’ due to intense competition from other 7[-]Eleven stores located in close proximity to its location.” *Id.* at 5.

When determining the duration of an NTSO, the Act provides that the Secretary must 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.” 21 U.S.C. § 333(f)(5)(B). The Act also provides that, when determining whether to impose, “compromise, modify, or terminate” an NTSO, the Secretary must “consider whether the retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products.” Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(G), (F)(i)-(iv). The FDA has issued guidance establishing the maximum duration for a retailer's first NTSO to be 30 calendar days. FDA Guidance at 4. The guidance states that the FDA will generally seek the maximum duration, but may reduce the time period when taking into consideration the factors listed in section 333(f)(5)(B) and the effective steps the retailer has taken to prevent the sale of tobacco products to minors. *Id.* at 3.

The ALJ weighed the factors listed in section 333(f)(5)(B), and determined that a 30-calendar-day NTSO is “reasonable” and “necessary.” ALJ Decision 7-9. The ALJ considered the nature, circumstances, extent, and gravity of Respondent’s violations, noting that Respondent had a history of five prior violations in addition to the violations documented on January 30, 2016. *Id.* at 7. The ALJ found that “Respondent’s repeated inability to comply with federal tobacco regulations raises a serious concern for the wellbeing of minors.” *Id.* The ALJ’s finding is consistent with Board precedent that each violation of the tobacco regulations is serious because it “contravenes federal laws enacted to protect minors from the adverse health effects associated with tobacco use.” *Vasudevay LLC, d/b/a Town News and Tobacco*, DAB No. 2746, at 4 (2016).

With respect to Respondent’s ability to do business, the ALJ noted that Respondent had “submitted no evidence in support of [his] contention that the imposition of an NTSO will put his franchise in jeopardy” and that “it is unclear whether Respondent could continue to operate as a business regardless of its status as a 7-Eleven franchise.” ALJ Decision at 8. Although Respondent faults the ALJ for not “giv[ing] any weight to his ‘testimony’” regarding the alleged harmful effects on his business, the statements Respondent made during the hearing, as the ALJ told him, did not constitute testimony because he had not put himself forward as a witness or submitted written direct testimony in advance of the hearing.<sup>5</sup> *Id.* at 6. Nonetheless, the ALJ did address Respondent’s arguments regarding the alleged adverse effects of the NTSO on his business. *Id.* at 8. The ALJ concluded that the available evidence would not support a conclusion “that a 30-day NTSO would severely hinder Respondent’s ability to continue other lawful retail operations during the NTSO period.” *Id.* Moreover, the ALJ concluded that “the need to protect the [minors] outweighs the adverse effects that an NTSO may have on an individual retailer’s business....” *Id.* (quoting *Kat Party Store, Inc., d/b/a Mr. Grocer Liquor Store*, CRD No. TB509, at 3 (2016)).

The ALJ concluded her analysis by finding that Respondent is “fully culpable for all five repeated violations,” and determining that there were no mitigating factors to justify reducing the duration of the NTSO. *Id.* at 9. Respondent does not challenge these findings on appeal. We find no basis to alter the ALJ’s decision to impose an NTSO for a duration of 30 calendar days.

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<sup>5</sup> Since we find no error in the ALJ’s decision not to treat Respondent’s statements as testimony for these reasons, we regard as dicta, and need not address, her further statement that Respondent could not both represent Respondent and give witness testimony. See ALJ Decision at 5.



**Conclusion**

We conclude that the ALJ Decision is legally sound and supported by substantial evidence. We affirm the ALJ Decision and sustain the 30-calendar-day NTSO entered by the ALJ.

\_\_\_\_\_/s/  
Leslie A. Sussan

\_\_\_\_\_/s/  
Constance B. Tobias

\_\_\_\_\_/s/  
Sheila Ann Hegy  
Presiding Board Member