

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

Chit-Chat Inc. d/b/a Scuttlebutts  
Docket No. A-19-15  
Decision No. 2936  
April 25, 2019

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

Chit-Chat Inc. d/b/a Scuttlebutts (Respondent) appeals the October 1, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a \$2,236 civil money penalty (CMP) against Respondent for four 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 24 months. *Chit-Chat Inc. d/b/a Scuttlebutts*, DAB TB3144 (2018) (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 August 23, 2017, 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 (photo ID) 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 May 3, 2016, and December 27, 2016, and failed to verify the age of a purchaser via photo ID on May 3, 2016. The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for the \$2,236 CMP.

On appeal, Respondent does not dispute the ALJ's findings that it sold tobacco products to a minor and also failed to verify the purchaser's age by means of photo identification. Nor does Respondent dispute the ALJ's conclusion that the CMP amounts are reasonable penalties for Respondent's violations. Instead, Respondent argues that CTP violated its due process rights because Respondent did not receive notification of the documented violations until six days after the August 23, 2017 inspection. Respondent also challenges the ALJ's treatment of evidence and discovery. For the reasons explained below, we reject Respondent's arguments and affirm the ALJ Decision.

## Applicable Law

The Family Smoking Prevention and Tobacco Control Act (TCA) amended the Act and instructed the Secretary to promulgate regulations restricting the sale, distribution, access, and promotion of cigarettes and smokeless tobacco to protect children and adolescents. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 (June 22, 2009). The Act, as amended, prohibits any “act with respect to . . . [a] tobacco product . . . held for sale . . . after shipment in interstate commerce” that results in the product being “misbranded” and authorizes the FDA to impose certain remedies against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333. A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under 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.” 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[.]” 21 C.F.R. §§ 1140.14(a)(1) and (a)(2)(i).<sup>1</sup>

CTP may seek to impose CMPs against “any person who violates a requirement of [the Act] which relates to tobacco products . . . .” 21 U.S.C. § 333(f)(9). The regulations set out a table of annually-adjusted CMP amounts that may be imposed for violations of the regulatory requirements, with CMPs increasing for successive violations within a given time period. 21 C.F.R. § 17.2 (adopting 45 C.F.R. § 102.3 (table)). In August 2017, the maximum CMP “in the case of a fourth tobacco product regulation violation within a 24-month period” was \$2,236. 45 C.F.R. § 102.3 (table).

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a “presiding officer” who is “an [ALJ] qualified under 5 U.S.C. 3105.” 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before the ALJ by serving a Complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The retailer (the respondent in the administrative

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<sup>1</sup> At the time of the FDA inspection on May 3, 2016, 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 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 respondent files a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

A respondent dissatisfied with an ALJ decision may appeal that decision (to which the regulations refer as the “initial decision”) to the DAB. *Id.* §§ 17.45, 17.47. The Board “may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by” the ALJ. *Id.* § 17.47(j).

## Case Background<sup>2</sup>

### 1. The Complaint and Hearing

On September 25, 2017, CTP served a Complaint (dated September 18, 2017) on Respondent seeking to impose a \$2,236 CMP for four violations of the Act and its implementing regulations within a twenty-four month period. ALJ Decision at 1-2; Complaint ¶ 1. The Complaint alleged that on August 23, 2017, 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 photo ID containing a date of birth in violation of 21 C.F.R. § 1140.14(a)(2)(i). Complaint ¶ 7. The Complaint specifically alleged that during the inspection, “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on August 23, 2017, at approximately 5:23 PM” and that “the minor’s identification was not verified before the sale, as detailed above, on August 23, 2017, at approximately 5:23 PM.” *Id.*

In addition to charging Respondent with the alleged violations found during the August 23, 2017 inspection, the Complaint noted that CRD had closed a prior CMP action involving a complaint filed by CTP against Respondent. ALJ Decision at 3; Complaint ¶¶ 9-10. In the prior CMP action, Respondent admitted to selling tobacco products to a minor on May 3, 2016, and December 27, 2016, and failing to verify the age of a person purchasing tobacco products by means of photo ID containing the bearer’s date of birth on May 3, 2016. ALJ Decision at 3; Complaint ¶¶ 9-10. Respondent “expressly waived its right to contest” the violations in subsequent actions. ALJ Decision at 3 (citing Complaint ¶ 10); CTP Ex. 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.

On October 24, 2017, Respondent filed an Answer to the Complaint. *Id.* at 2. Respondent argued, among other things, that: 1) CTP did not timely notify Respondent of the August 23, 2017 violations; 2) the minor did not obtain a receipt of the transaction; and 3) CTP erred by counting multiple violations against Respondent from a single inspection. Answer at 2.

On November 2, 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. The parties subsequently filed separate motions seeking protective orders for documents requested by the opposing party. CTP sought to protect documents responsive to Respondent's request for "[d]ocumentation displaying the selection and training of the FDA tobacco inspectors." CTP Motion for Protective Order at 2. CTP argued that the documents responsive to Respondent's request were "irrelevant to the issues of this case" and exempt from disclosure under 21 C.F.R. § 20.64. *Id.* at 6-8. On January 8, 2018, the ALJ established a January 16, 2018 deadline for Respondent to file a response to CTP's motion. *See* Amended By Direction Letter at 1. On January 29, 2018, the ALJ issued an order (ALJ Order) in which she granted CTP's motion for a protective order after finding that Respondent had not filed a response to CTP's motion. ALJ Order at 5.

On March 29, 2018, CTP filed a pre-hearing brief, a list of proposed witnesses and exhibits, and 14 numbered exhibits, including the sworn written direct testimony of the inspector who documented the alleged August 23, 2017 violations and a CTP senior regulatory counsel. ALJ Decision at 2. On April 27, 2018, Respondent filed a pre-hearing brief (Resp. Pre-Hearing Br.), but did not proffer any proposed exhibits or propose any witnesses. *Id.*

In its pre-hearing brief, Respondent argued that it should not be liable for failing to verify the age of a minor purchaser by means of photo ID because minors in undercover buy operations in Massachusetts do not carry photo IDs that can be provided to retail establishments. Pet. Pre-Hearing Br. at 2, 5. Respondent further argued that, because undercover minors do not carry IDs, if a retail establishment sells tobacco products to a minor, the establishment will automatically violate the regulation for verifying the minor's age as well. *Id.* at 2. Respondent stated that it did not receive notice of the August 23, 2017 inspection until six days after the inspection was conducted. *Id.* at 3. Respondent asserted that it was therefore unable to review videotape of the alleged transaction, and that the cashier on duty did not recall the incident. *Id.* at 3-4. Respondent also noted that the inspector remained outside of the establishment and did not personally witness the transaction, and implied that the minor's recollection of the inspection is "unreliable hearsay." *Id.* at 5.

The ALJ held a pre-hearing conference on June 1, 2018. ALJ Decision at 2. On July 10, 2018, the ALJ held a hearing via telephone, during which she admitted into evidence CTP's proposed exhibits and heard cross-examination and re-direct examination testimony from the inspector. *Id.* CTP and Respondent each filed post-hearing briefs on August 20, 2018. *Id.* In its Post-Hearing Brief, Respondent reiterated its arguments that it was not timely notified of the August 23, 2017 inspection, and that it was not liable for failing to verify the minor's age because the minor did not have a photo ID in his possession.

## 2. The ALJ Decision

On October 1, 2018, the ALJ issued her decision imposing a \$2,236 CMP against Respondent, concluding that CTP showed "by a preponderance of the evidence" that "Respondent committed four violations of the Act and its implementing regulations within a 24-month period." ALJ Decision at 9. The ALJ first determined that, "[i]n settling the prior complaint, Respondent not only admitted the [May 3, 2016 and December 27, 2016] violations occurred, but also waived the right to contest the violations in the future and stated that it understood that the admitted violations may be counted in determining the total number of violations for future enforcement actions." *Id.* at 3 (citing Complaint ¶ 10). The ALJ then relied on the inspector's testimony and corroborating evidence to find that Respondent violated 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) on August 23, 2017. The ALJ also found that "Respondent failed to establish any affirmative defense by a preponderance of the evidence." *Id.* at 9 (citing 21 C.F.R. § 17.33(c)). Having found Respondent liable for the violations, the ALJ proceeded to determine that the penalty amount of \$2,236 is "reasonable and appropriate under 21 U.S.C. §§ 303(f)(5)(B) and 333(f)(9)." *Id.* at 11.

In reaching her conclusions, the ALJ rejected Respondent's argument that its right to due process was violated because it was not informed of the inspection and alleged violations until six days after the inspection took place. The ALJ stated, in relevant part:

[T]he evidence shows that CTP sent Respondent the Notice [of Compliance Check Inspection] on August 25, 2017, and Respondent received the Notice on August 29, 2017; which I find to be sufficiently timely. Respondent contends that its security camera overwrites the video tape every 4-5 days and thus Respondent was unable to review the sale footage. Respondent, however, provided no evidence that receiving the Notice on the sixth day rather than the fourth or fifth day prevented the necessary review as asserted. Even if I accept Respondent's allegations as true, given Respondent's history of past violations, Respondent had notice of the significance in preserving evidence and ample opportunity to change how it preserves its security tapes prior to the current violations.

*Id.* at 6. The ALJ also considered and rejected Respondent’s arguments, among others, that the minor did not obtain a receipt of the transaction; that the minor’s recollection of what occurred in the establishment is unreliable hearsay; and that it could not be liable for a violation of section 1140.14(a)(2)(i) because the minor did not have a photo ID in his possession. *Id.* at 6-9.

### **Standard of review**

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

### **Analysis**

As indicated above, the scope of the appeal before us is limited. In its request for review (RR) and reply brief (Reply), Respondent does not dispute the ALJ’s findings that Respondent sold cigarettes to a minor and failed to verify the minor’s age by means of photo ID on August 23, 2017, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), nor does Respondent dispute the ALJ’s conclusion that the \$2,236 CMP sought by CTP is an appropriate remedy for four violations of the Act and its implementing regulations over a period of 24 months. Rather, Respondent argues that its due process rights were violated because it did not receive notification of the documented violations until six days after the August 23, 2017 inspection. Respondent also argues that it should have been allowed to introduce documents allegedly relating to its prior violations, and challenges the ALJ’s ruling granting a protective order to CTP for documents relating to the selection and training of FDA tobacco inspectors. For the following reasons, we conclude that Respondent’s arguments are meritless.

#### **I. *CTP provided timely notice of the violations documented at Respondent’s establishment on August 23, 2017.***

Before the Board, Respondent renews its argument that CTP did not provide timely notice of the violations documented at its establishment on August 23, 2017. RR at 2; Reply at 1, 2. A document titled Compliance Check Inspection Notice (Notice) was delivered to Respondent’s retail address via the United Parcel Service (UPS) on August 29, 2017 – six days after the inspection date. CTP Exs. 10, 11. The Notice informed Respondent that its retail establishment “was inspected on 08/23/2017 at approximately 05:23 PM,” that “[a]n FDA commissioned inspector reported that a minor was able to enter [Respondent’s] establishment and purchase cigarettes in a package,” and that “[o]ther potential violations of federal tobacco laws may have also been reported by the inspector . . . .” Notice at 1. Respondent argues that the six-day delay between the date

of the inspection and the date that the Notice was delivered violated Respondent's due process rights because it prevented Respondent from gathering exculpatory evidence. RR at 2. Respondent asserts that the video security system used in its retail establishment "rewrites over the CD every 4-5 days" and, thus, no video footage of the alleged transaction now exists. *Id.* Respondent also asserts that the cashier on duty has no recollection of the transaction. *Id.* Respondent posits that it should have been notified of the violations at the time of the inspection. *Id.* at 2; Reply at 2.

We reject Respondent's arguments. The only notice requirements that Congress has imposed on CTP are "for 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. TCA § 103(q)(1)(B), (D) (emphasis added). Regarding the first requirement, the Board has held that "the provision 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 . . . ." *Atty's Parti Expo, Inc., d/b/a Parti Expo*, DAB No. 2925, at 12-13 (2019) (quoting *Orton Motor Co., d/b/a Orton's Bagley*, DAB No. 2717, at 19 (2016), *aff'd*, *Orton Motor, Inc., d/b/a Orton's Bagley v. United States Dep't of Health & Human Servs.*, 884 F.3d 1205 (D.C. Cir. 2018)). Here, CTP met this requirement when it sent Respondent the May 12, 2016 FDA Warning Letter notifying Respondent of the violations found on the first inspection (May, 3, 2016). *See* CTP Ex. 12; *Atty's* at 13. Respondent does not dispute that CTP notified it of its prior violations before initiating its administrative enforcement actions, and the Complaint for the present enforcement action states the relevant prior violations. Complaint ¶9. Neither the statutes nor the regulations require CTP to give retailers notice of violations at the time of an inspection; nor do they require CTP to send a Notice of Compliance Check Inspection **after** a follow-up inspection, much less impose any timing or manner of service requirements for sending it.<sup>3</sup> Thus, we find no error in the ALJ's conclusion that the Notice was "sufficiently timely." ALJ Decision at 6.

Respondent also attempts to inject policy arguments into its appeal. *See, e.g.*, RR at 2 ("Respondent is concerned because notice not given during [the] time of inspection puts our youth at risk . . . if there is an employee of the company not doing their job properly."); Reply at 1 (CTP "is more concerned about the term "sufficiently timely" than working on a better system to notify the business owner of a potential problem quicker."). Neither the ALJ nor the Board, however, have the "authority to make policy for the FDA." *TOH, Inc., d/b/a Ridgeville Service Center*, DAB No. 2668, at 13 (2015).

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<sup>3</sup> The regulations require CTP to file and serve an administrative complaint to initiate an action seeking civil money penalties, and there is no dispute that CTP complied with that requirement here. 21 C.F.R. § §17.5, 17.7.

## II. *Respondent's evidentiary arguments have no merit.*

Respondent states that it “was not allowed to introduce” into evidence documents allegedly related to its prior CMP action. RR at 1-2; Reply at 1-3. Before the ALJ, Respondent stated that in a previous inspection which documented Respondent’s settled violations, the inspector “took a picture of a pizza place called Wicked Pizza and said the violation occurred there” rather than at Respondent’s establishment. Answer ¶ 4. Respondent now states that documents relating to this prior inspection would show “the potential” for CTP to issue “an incorrect decision” and would therefore “have been significant in preparing a defense.” RR at 1.

Respondent did not submit any proposed exhibits in the ALJ proceeding (despite having ample opportunity to do so). *See* Tr. at 11-12. Accordingly, the ALJ could not have refused to admit the alleged document from a previous inspection. In the ALJ’s November 2, 2017 APHO, the ALJ instructed Respondent that its pre-hearing exchange should consist of “[a] list of all proposed exhibits,” and “[a] copy of each proposed exhibit.” APHO at 3. On April 27, 2018, Respondent submitted an informal brief in accordance with the ALJ’s instructions, but did not include a list of proposed exhibits or a copy of any proposed exhibit.

In any event, the ALJ would have been required to exclude the alleged document regarding a prior inspection had Respondent submitted it as evidence because it is not relevant or material to this case. *See* 21 C.F.R. § 17.39(c) (“The presiding officer [ALJ] shall exclude evidence that is not relevant or material.”). Respondent admits that it “electronically signed the settlement” for the previous violations, and waived its ability to contest the violations in the future. RR at 1; CTP Ex. 2. While Respondent argues that it intended to use evidence relating to the prior inspection only to establish that CTP could err in documenting violations, such evidence would have no bearing on the factual issues before the ALJ of whether Respondent sold tobacco products to a minor and failed to verify the minor’s age by means of photo ID on August 23, 2017. Moreover, Respondent does not dispute here the ALJ’s findings of fact regarding the August 23, 2017, sale and failure to verify.

Respondent also argues that the ALJ erred in granting a protective order to CTP for documents relating to the selection and training of FDA tobacco inspectors. RR at 1-2; Reply at 1-3. CTP filed the motion for a protective order on December 21, 2017. The ALJ had previously instructed Respondent in her APHO that “[t]he proponent of the document request shall, within 15 days of receiving the memorandum in support of the motion for a protective order, file a response specifying why the other party should produce the requested documents.” APHO at 7 (emphasis removed). On January 8, 2018, the ALJ established a deadline of January 16, 2018, for Respondent to file a



response to CTP's motion. *See* Amended By Direction Letter at 1. Respondent did not file a response by that date, and on January 29, 2018, the ALJ granted CTP's motion for a protective order.

Respondent states before the Board that it did not file a response because it "felt the request [for production of documents] was straightforward" and understood the response to be "optional." RR at 2; Reply at 2-3. Respondent also states that the ALJ did not detail "what would happen if the information was not provided." Reply at 3. These statements provide no basis to disturb the ALJ's ruling granting the protective order. Compliance with ALJ orders is not optional. ALJs have the authority to "[r]egulate the scope and timing of discovery consistent with" 21 C.F.R. § 17.23. *See* 21 C.F.R. § 17.19(b)(7). The regulations found at section 17.23 provide that "[t]he burden of showing that documents should be produced is on the party seeking their production." *Id.* § 17.23(d)(3). The ALJ established a January 16, 2018 deadline for Respondent to satisfy this burden consistent with the regulations – a deadline which Respondent did not meet. In addition, the regulations provide for a discovery process limited to "documents that are relevant to the issues before the presiding officer." *Id.* § 17.23(a). The only issues before the ALJ in this case were whether Respondent in fact sold cigarettes to a minor and failed to verify the minor's age on August 23, 2017, and whether the \$2,236 CMP was an appropriate remedy, and Respondent does not dispute that the sale and failure to verify occurred on that date. How the inspector was trained is not relevant since Respondent does not dispute the inspector's findings, which the ALJ found supported by the record.

## Conclusion

For the foregoing reasons, we affirm the ALJ Decision and sustain the \$2,236 CMP entered by the ALJ.

\_\_\_\_\_/s/  
Christopher S. Randolph

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

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