

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

Auto Valet, Inc. d/b/a Finest Car Wash  
Docket No. A-18-61  
Decision No. 2915  
December 13, 2018

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

Auto Valet, Inc. d/b/a Finest Car Wash (Respondent) appeals the March 29, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a \$550 civil money penalty (CMP) against Respondent for three 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. *Auto Valet, Inc. d/b/a Finest Car Wash*, DAB TB2571 (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). The ALJ found by a preponderance of the evidence that during an FDA inspection on October 23, 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 (photo ID) containing a date of birth, that the purchaser was 18 years of age or older. The ALJ also found that Respondent previously sold tobacco products to a minor, and failed to verify the age of a purchaser via photo ID, on July 21, 2015. The ALJ concluded that the evidence of record provided a basis for imposing a \$550 CMP.

On appeal, Respondent argues only that a retailer is not required to verify a tobacco product purchaser's date of birth by means of photo ID if the purchaser appears to be over the age of 26. 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 of Health and Human Services (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 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).<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). 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 October 2016, the maximum CMP “in the case of a third tobacco product regulation violation within a 24-month period” was \$550. 45 C.F.R. § 102.3 (table). The 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).

A respondent dissatisfied with an ALJ decision may appeal that decision (which the regulations refer to as the “initial decision”) to the Departmental Appeals Board (Board). 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).

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<sup>1</sup> At the time of the first FDA inspection 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 sections 1140.14(a)(1) and 1140.14(a)(2), respectively. 81 Fed. Reg. 28,973, 28,974, 29,103 (May 10, 2016); *see* <https://www.gpo.gov/fdsys/granule/FR-2016-05-10/2016-10685>. We cite only to the current version of the regulations.

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

### 1. Summary of the Undisputed Facts

CTP served a Complaint (dated April 3, 2017) on Respondent at Respondent's place of business, in which CTP sought to impose a \$550 CMP as a remedy for three violations of FDA's tobacco regulations over a period of 24 months.<sup>3</sup> ALJ Decision at 2; Complaint ¶ 1. The Complaint alleged that CTP issued a Warning Letter<sup>4</sup> to Respondent on August 27, 2015, alleging that on July 21, 2015, Respondent committed two 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). ALJ Decision at 3-4; Complaint ¶¶ 11-12. According to the Complaint, during the inspection on July 21, 2015, "a person younger than 18 years of age" was able to purchase a package of Newport Box 100s cigarettes and the minor's identification was not verified before the sale. *See id.* On October 23, 2016, an FDA-commissioned inspector inspected Respondent's establishment and found the following violations: 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). ALJ Decision at 4; Complaint ¶ 9. The Complaint alleged that "a person younger than 18 years of age" was able to purchase a package of Marlboro cigarettes and that the minor's identification was not verified before the sale. *See id.*

Respondent filed an Answer to the Complaint dated May 5, 2017, in which it denied the allegations. ALJ Decision at 2; CRD Dkt. Entries 4, 4a. On May 15, 2015, the ALJ issued an Acknowledgment and Pre-hearing Order (APHO) which acknowledged receipt of the Answer and established procedural deadlines. CRD Dkt. Entry 5. On July 13, 2017, Respondent filed a motion for a protective order. CRD Dkt. Entry 9. On July 27, 2017, the parties jointly filed a Stipulation of Fact, stating that "Respondent has the financial means to pay \$550 if liability is assessed" and that a "[p]ayment of \$550 will not constitute a financial hardship for Respondent." CRD Dkt. Entry 10. On August 1,

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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.

<sup>3</sup> At all times relevant to this appeal, Respondent's business location was 36 Pleasant Valley Parkway, Providence, Rhode Island 02908.

<sup>4</sup> Respondent was identified in the Warning Letter as "Irving #1 Finest Car Wash." ALJ Decision at 3 n.4; Complaint ¶ 12.

2017, the ALJ issued a partial protective order in response to Respondent's motion. On September 6, 2017, CTP filed a prehearing brief, a list of proposed witnesses and exhibits, and 21 numbered exhibits, including three written witness declarations. CRD Dkt. Entries 13, 13a-13v.

On September 26, 2017, Respondent filed a prehearing brief (R. Pre-Hearing Br.), a list of proposed witnesses and exhibits, and five numbered exhibits, including one written witness declaration. CRD Dkt. Entries 14, 14a-14e. Respondent argued in its prehearing brief "that if a purchaser of cigarettes appears to be over 26 years old, then the retailer need not verify the purchaser's age by requiring a photo ID" under section 1140.14(a)(2). R. Pre-Hearing Br. at 3-4. Respondent asserted that its staff relied on a publication from the state of Rhode Island stating that a retailer should "ask for a photo ID of anyone who appears to be under 27." *Id.* at 4 (citing R. Ex. 2). Respondent also asserted that FDA guidance documents confirm Respondent's interpretation of the regulation. *Id.* Respondent argued that CTP's delay between the date of the July 21, 2015 violations and the date that Respondent was notified of the violations in the August 27, 2015 Warning Letter "substantially prejudiced [Respondent's] ability to defend his business." *Id.* at 5. Respondent also argued that the CMP should be mitigated because Respondent previously passed five undercover inspections and made efforts to prevent the sale of tobacco products to minors.

Respondent filed a supplemental brief on September 27, 2017 stating that it discovered an ALJ decision that reads, "[t]he regulations do not take into consideration the retailer's subjective belief that a purchaser is a particular age." CRD Dkt. Entry 15 (R. Supplemental Br.) at 1 (quoting *C K Food and Fuel MN Inc. d/b/a C K Food and Fuel*, DAB TB1622, at 3 (2017)). Respondent stated that *C K* is "erroneous, would render the language of the regulation in [section 1140.14(a)(2)] meaningless, and ignores the common-sense interpretation that Respondent has suggested in its [pre-hearing brief], which Respondent maintains is the only reasonable, practical interpretation." *Id.* at 2.

The ALJ held a hearing on December 5, 2017, during which no witnesses were cross-examined. *See* CRD Dkt. Entry 18 (Hearing Transcript). CTP and Respondent each filed post-hearing briefs on February 16, 2018. CRD Dkt. Entries 21, 22. In its post-hearing brief, Respondent again argued, *inter alia*, that a retailer is not required to verify a tobacco purchaser's age by means of photo ID if the purchaser appears to be over the age of 26. R. Post-hearing Br. at 1-3. Respondent also argued that "each inspection upon which a sales clerk failed to check ID and sold to a minor should be counted as one violation . . . ." *Id.* at 3.

## 2. The ALJ Decision

The ALJ issued his decision imposing a \$550 CMP against Respondent, finding that CTP showed “by a preponderance of the evidence” that Respondent violated 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) on July 21, 2015 and October 23, 2016, by selling tobacco products to minors and failing to verify that the tobacco product purchasers were of sufficient age. ALJ Decision at 12-14. The ALJ relied on the testimony of the inspectors who documented the violations, finding the testimony “believable and supported by evidence in the record.” *Id.* at 16. The ALJ also found that “Respondent has not provided any affirmative proof to rebut the evidence of noncompliance presented by CTP.” *Id.* at 5. Having found Respondent liable for the violations, the ALJ proceeded to determine that a penalty amount of \$550 is “appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).” *Id.* at 20.

In reaching his conclusions, the ALJ rejected Respondent’s due process argument that the delay between the July 21, 2015 violations and the August 27, 2015 Warning Letter “substantially prejudiced” Respondent from defending itself, finding that the current action “provides a meaningful opportunity” for Respondent “to be heard” regarding the July 21, 2015 violations. *Id.* at 15 (citing *Orton Motor, Inc. D/B/A Orton’s Bagley v. U.S. Dep’t of Health and Human Servs.*, 884 F.3d 1205 (D.C. Cir. Mar. 20, 2018)). The ALJ also rejected Respondent’s argument that CTP erred in its method of counting violations, finding that “CTP’s policy of counting violations has been held to be consistent with the language of the [Act] and its implementing regulations.” *Id.* at 16 (citing *Orton*). Finally, the ALJ rejected Respondent’s argument that a retailer need not verify the age of a tobacco purchaser if the purchaser appears to be over the age of 26, reasoning that he is “not required to make a determination whether it is reasonable for a retailer to conclude that a tobacco product purchaser appears to be over the age of 26” because “the regulations do not take into account a retailer’s subjective inquiry about the appearance of tobacco product purchasers.” *Id.* at 15.

### **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**

Preliminarily, we note that, except for a general denial in its Answer to the Complaint, Respondent did not dispute, through documents or testimony, or in its briefs, CTP’s evidence showing that Respondent sold tobacco products to minors on the dates specified in the Complaint without checking identification for proof that the purchasers were at

least 18 years old. *See* R. Exs. 1-5.<sup>5</sup> Rather than dispute these facts, Respondent argued below, as it does here, that CTP failed to meet its evidentiary burden of production because CTP failed to show that the undercover purchasers looked younger than 26 years of age (thus triggering the requirement that Respondent ask for proof of age prior to selling tobacco products to the undercover purchasers). *See* R. Pre-Hearing Brief at 2; R. Post-Hearing Brief at 3 (“[T]he Government refuses even to reveal photographs showing the appearance of its testers for [Respondent] and the Presiding Officer to review.”) Below we explain why Respondent’s arguments provide no basis for us to disturb the ALJ’s decision.

The regulation at 21 C.F.R. § 1140.14(a)(2) provides—

- (i) Except as otherwise provided in paragraph (a)(2)(ii) of this section and in § 1140.16(c)(2)(i), each retailer must verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the product is younger than 18 years of age;
- (ii) No such verification is required for any person over the age of 26[.]

Respondent maintains that the ALJ erred in his interpretation of 21 C.F.R. § 1140.14(a)(2), and argues that the regulation should be interpreted to mean that “a retailer’s sales clerk is not required to verify a purchaser’s age by ID where the clerk reasonably perceives from appearance that the purchaser is over age 26 . . . [.]” Request for Review (RR) at 2-3. Respondent argues that the ALJ’s interpretation of section 1140.14(a)(2) either renders the regulation “meaningless” or “re-writes” it. Respondent further argues that its due process rights have been violated because section 1140.14(a)(2) “is inartfully drafted, does not make sense on its face, and does not make sense as interpreted by the ALJ . . . .” *Id.*

We reject Respondent’s arguments. The Board has previously considered and rejected the argument that section 1140.14(a)(2) incorporates an “appearance” or “judgment” standard. *Deli-Icious Catering, Inc. d/b/a Convenient Food Mart*, DAB No. 2812, at 11 (2017) (The regulations “do not incorporate any ‘appearance’ or ‘judgment’ standard and instead require that retailers check photo IDs of *all* persons aged 26 and younger who seek to purchase cigarettes.”). Respondent argues that retailers “need not engage in mental gymnastics to understand what is required of them” and “must be able to rely on an ordinary person’s understanding of plain English . . . .” RR at 3. No mental gymnastics are required here because we find no ambiguity in the text of the regulation. On its face, section 1140.14(a)(2) establishes a wholly objective standard, i.e., a retailer

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<sup>5</sup> Rather than dispute that it sold tobacco to a minor on October 23, 2016, Respondent instead asserts that it fired the clerk who was on duty during that incident. R. Ex. 1, at 2, ¶ 7.

must verify by means of photo ID the age of every person aged 26 and under. The plain language of the regulation does not provide an exception to this requirement for purchasers who appear to be older than age 26 but are actually under 26. We therefore agree with CTP when it states that “Respondent’s interpretation conflicts with the plain language of the regulation as it necessarily requires that words be read into the regulation where they do not otherwise exist.” CTP’s Memorandum in Opposition to Respondent’s Appeal at 4; *see also Omni Manor Nursing Home*, DAB No. 2374, at 4-5 (2011) (and cases cited therein) (“[T]he Board has declined to read into a statute or regulation limitations not present on the face of the statute or regulation itself.”). In other words, the regulation at section 1140.14(a)(2) is clear on its face, and we are bound to apply it by its terms. *Orton Motor Co., d/b/a Orton’s Bagley*, DAB No. 2717, at 14 (2016) (“Where the applicable law is clear, we apply it by its terms.”), *aff’d*, *Orton Motor, Inc.*, 884 F.3d 1205; *see also* 21 C.F.R. § 17.19(c) (“presiding officer does not have the authority to find . . . regulations invalid”).

Moreover, the Board in *Deli-Icious* found that the drafters of the 1996 final rule excepting persons over age 26 from the requirement of verifying the age of cigarette purchasers “explicitly rejected an ‘appearance’ standard and made clear that retailers must check the IDs of *every* purchaser age 26 years and younger . . . .” *Deli-Icious* at 11 (emphasis in original). In support of its finding, the Board quoted the preamble to the 1996 final rule, which states in relevant part—

One comment . . . contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; . . . . Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age.

The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person’s age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person “looked” like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

*Id.* (quoting 61 Fed. Reg. 44,396, 44,439 (Aug. 28, 1996)).

Respondent contends that it “reasonably relied” on a passage found in an FDA guidance document published in 2014, which states in full—

Retailers who have in-store videotaping should periodically review the tapes to ensure that employees are complying with sales to minor laws and store policies related to reducing the illegal sale of cigarettes and smokeless tobacco to underage youth. Specifically, retailers should review the tapes to ensure that store employees are requesting and examining photographic identification from customers **who appear to be** under the age of 27.

R. Ex. 3 (*Tobacco Retailer Training Programs (Revised)* at 16 (June 2014) (emphasis added) (hereafter “2014 FDA Guidance”)).<sup>6</sup> Respondent argues that, “in light of CTP’s own [g]uidance that industry should rely on the appearance of purchasers, principles of equitable estoppel should preclude CTP from suggesting otherwise.” RR at 4-5. The plain language of the provision in the 2014 FDA Guidance that Respondent claims to have relied on, however, which is found in a subsection detailing management practices that retailers should implement as part of a retailer training program, merely recommends that retailers with in-store videotaping review the tapes to ensure that employees are checking the photo IDs of customers who appear to be under the age of 27. The provision does not offer the agency’s interpretation of section 1140.14(a)(2), much less create a subjective appearance exception to the requirement that retailers check the photo ID of every tobacco purchaser aged 26 years and younger.

In any event, Respondent has not provided any authority showing that the equitable remedy of estoppel is even available in this administrative case. Both the Board and courts have questioned whether equitable estoppel can ever lie against the government, and concluded that the remedy would require, “at a minimum, a showing that the traditional requirements for estoppel are present (i.e., a factual misrepresentation by the government, reasonable reliance on the misrepresentation by the party seeking estoppel, and harm or detriment to that party as a result of the reliance) and that the government’s employees or agents engaged in affirmative misconduct.” *Ill. Dep’t of Children and Family Servs.*, DAB No. 2734, at 8 (2016) (internal quotation marks omitted) (quoting *Oaks of Mid City Nursing & Rehab. Ctr.*, DAB No. 2375, at 31 (2011) (citing *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 421 (1990) and *Pacific Islander Council of Leaders*, DAB No. 2091, at 12 (2007) (“[E]quitable estoppel does not lie against the federal government, if indeed it is available at all, absent at least a showing of affirmative misconduct.”))). Respondent has failed to make these showings.

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<sup>6</sup> CTP updated the 2014 FDA Guidance three times in 2018. The current document, revised in August 2018, states that “retailers should review the tapes to ensure that store employees are requesting and examining photographic identification from customers **who are** under the age of 27”. *Tobacco Retailer Training Programs (Revised)* at 19 (emphasis added) (available at <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulations/Guidance/UCM218906.pdf>).



**Conclusion**

For the foregoing reasons, we affirm the ALJ Decision and sustain the \$550 CMP entered by the ALJ.

\_\_\_\_\_/s/  
Sheila Ann Hegy

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

\_\_\_\_\_/s/  
Christopher S. Randolph  
Presiding Board Member