

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

Monroe Mobil, Inc. d/b/a BP
Docket No. A-18-98
Decision No.2918
December 20, 2018

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

Monroe Mobil, Inc. d/b/a BP (Respondent) appeals the May 31, 2018 initial decision of an Administrative Law Judge (ALJ) imposing a 30-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. *Monroe Mobil, Inc. d/b/a BP*, DAB TB2767 (2018) (ALJ Decision). The ALJ issued his decision following a hearing on an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) in which CTP alleged that during an FDA inspection on December 1, 2016, Respondent's staff sold a package of cigarettes to a person younger than 18 years of age. The Complaint also alleged that Respondent previously sold tobacco products to a minor, and failed to verify the age of a purchaser via photographic identification, on July 4, 2014, November 8, 2014, and September 11, 2015. The ALJ concluded that the evidence of record supported the allegations in the Complaint and provided a basis for imposition of a 30-day NTSO.

For the reasons set out below, we affirm the ALJ's decision.

Applicable Law

On June 22, 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA), which amended the Act and instructed the Secretary 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)(i).¹

CTP may seek to impose civil money penalties (CMPs) against “any person who violates a requirement of [the Act] which relates to tobacco products” 21 U.S.C. § 333(f)(9). CTP may also seek to impose a NTSO (alone or in addition to a CMP) when it finds “that a person has committed repeated violations of restrictions promulgated under section 387f(d) . . . at a particular retail outlet” *Id.* § 333(f)(8). “Repeated violations” is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation. . . .” TCA § 103(q)(1)(a); *see also* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3, 5-6, available at <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308>.

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

¹ At the time of the FDA inspections leading to Respondent’s prior violations, 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/pkg/FR-2016-05-10/pdf/2016-10685.pdf>.

The regulations permit a retailer to appeal a NTSO by requesting a hearing before a “presiding officer” who is “an [ALJ] qualified under 5 U.S.C. 3105.” 21 C.F.R. §§ 17.3(c), 17.9(a). CTP initiates a case before the ALJ by serving a complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB). The retailer (the respondent in the administrative appeal proceedings) requests a hearing by filing an answer to the complaint within 30 days but may request one 30-day extension. *Id.* § 17.9(a), (c). Assuming a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

A respondent dissatisfied with an ALJ decision may appeal that decision (which the regulations refer to as the “initial decision”) to the DAB. 21 C.F.R. §§ 17.45, 17.47. The Board “may decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion), or reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined by” the ALJ. *Id.* § 17.47(j).

Case Background²

1. The Complaint and the Hearing

On April 20, 2017, CTP served a Complaint (dated April 19, 2017) on Respondent at its place of business, 2731 Monroe Street, Dearborn, Michigan 48124. ALJ Decision at 2; CRD Docket (Dkt.) Entries 1, 1b. The Complaint sought to impose a NTSO as a remedy for five repeated violations of FDA’s tobacco regulations over a period of 36 months, to include the period from November 8, 2014 to December 1, 2016. Complaint ¶ 1. The Complaint alleged that on December 1, 2016, an FDA-commissioned inspector inspected Respondent’s retail establishment and found that Respondent impermissibly sold tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a)(1). *Id.* ¶ 6. The Complaint specifically alleged that during the inspection, “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on December 1, 2016 at approximately 4:07 PM.” *Id.*

In addition to charging Respondent with the alleged violation found during the December 1, 2016 inspection, the Complaint stated that the CRD had closed two prior CMP actions involving complaints filed by CTP against Respondent. Complaint ¶¶ 8-11. In the first of two prior actions, Respondent admitted to selling tobacco products to a minor and failing to verify the age of a person purchasing tobacco products by means of

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

photographic identification containing the bearer's date of birth on July 4, 2014 and on November 8, 2014. *Id.* ¶ 9. In the second prior action, Respondent admitted to similar violations on September 11, 2015.³ *Id.* ¶ 10. In both actions Respondent "expressly waived its right to contest" the violations in subsequent actions. *Id.* ¶¶ 9, 10.

On May 22, 2017, Respondent filed an Answer to the Complaint. ALJ Decision at 2; CRD Dkt. Entry 3. The ALJ issued an Acknowledgment and Pre-hearing Order (APHO) on May 25, 2017, which acknowledged receipt of the Answer and established procedural deadlines. ALJ Decision at 2; CRD Dkt. Entry 4.

On August 14, 2017, CTP filed its pre-hearing exchange, which included a pre-hearing brief. CTP identified one witness (J. Bishop, the FDA-commissioned inspector who visited Respondent's establishment on December 1, 2016) and submitted 21 numbered exhibits, one of which was Inspector Bishop's declaration offered as his written direct testimony. ALJ Decision at 2-3; CRD Dkt. Entries 7, 7a-7v. On August 22 and 23, 2017, Respondent filed a "Plan of Action Letter" describing the steps it already has taken and intends to take in the future to ensure compliance with the applicable requirements and two unmarked photographs purportedly evidencing a remedial action taken. ALJ Decision at 3; CRD Dkt. Entries 9, 9a, 10. On August 31, 2017, Respondent filed a witness list indicating its intent to call two witnesses at hearing. ALJ Decision at 3; CRD Dkt. Entry 13. On October 31, 2017, the ALJ held a pre-hearing conference during which the ALJ explained that the purpose of convening a hearing would be to admit exhibits and permit the parties to cross-examine witnesses and noted that Respondent had not submitted exhibits or the written direct testimony of the two witnesses in compliance with his APHO. The ALJ then issued an order on November 9, 2017, allowing Respondent until November 17, 2017 to supplement its pre-hearing exchange, subject to a showing of good cause. ALJ Decision at 3; CRD Dkt. Entry 15. On November 17, 2017, Respondent filed the sworn affidavits of its two proposed witnesses and a "Petition to Permit [Respondent] to Introduce Two Affidavits at Trial." ALJ Decision at 3; CRD Dkt. Entry 16. CTP filed its opposition to Respondent's petition contending that good cause was not shown for the late filing. ALJ Decision at 3-4; CRD Dkt. Entry 18. On December 21, 2017, the ALJ denied Respondent's petition and excluded the proposed witness testimony from the record for late submission without a satisfactory explanation of good cause. ALJ Decision at 4; CRD Dkt. Entry 20.

³ CTP labels each violation that occurred on July 4, 2014 as an "original violation" (for which a warning letter was issued, with no CMP) and each violation that occurred on November 8, 2014, September 11, 2015 and December 1, 2016 as a "repeated violation" for the purposes of seeking a NTSO. CTP cited a total of five "repeated violations" – two on November 8, 2015 (failure to check ID; sale to a minor); two on September 11, 2015 (same); and one on December 1, 2016 (sale to minor). *See* Complaint ¶ 1 (and the table that follows).

On February 1, 2018, the ALJ held a hearing via telephone. ALJ Decision at 4. During the hearing, the ALJ admitted CTP's 21 exhibits, overruling Respondent's objections to the admissibility of the photocopy of the minor's redacted driver's license (redacted ID, marked as CTP Ex. 3) for lack of foundation. ALJ Decision at 4 (citing Hearing Transcript [CRD Dkt. Entry 22] at 7-9). The ALJ also heard cross-examination and re-direct testimony of Inspector Bishop. *Id.* (citing Hearing Transcript at 10-16, 17-20).

Respondent filed a post-hearing brief on April 9, 2018, arguing that the redacted ID was "not properly admitted into evidence." Post-hearing Brief [CRD Dkt. Entry 24] at 3. Respondent quoted Inspector Bishop's testimony, and argued that the inspector did not see the ID presented to the cashier working at Respondent's establishment on December 1, 2016 and therefore could not testify as to whether the ID (redacted) in the record is the ID that was presented to the cashier on December 1 or the ID's chain of custody from the minor to CTP. *Id.* at 1-3 (quoting Hearing Transcript at 11, 13, 14, 16). Citing Rule 602 of the Federal Rules of Evidence (Fed. R. Evid.),⁴ Respondent argued that Inspector Bishop's testimony regarding the redacted ID was "classic hearsay" for which none of the hearsay exceptions in Fed. R. Evid. Rule 803 apply. *Id.* at 3. Respondent contended that, "based on the flawed redacted driver's license," CTP could not "prove that Respondent's cashier sold cigarettes to a minor" and the case "should be dismissed." *Id.* at 4.

2. The ALJ Decision

The ALJ issued a decision imposing a NTSO for 30 consecutive calendar days. Preliminarily, the ALJ found Respondent's argument that the redacted ID was improperly admitted into evidence was "misguided and speculative." ALJ Decision at 9. The ALJ found "that the probative value of the redacted driver's license . . . is not substantially outweighed by the danger of unfair prejudice or confusion of the issues," and that the redacted license "is relevant and reliable." *Id.* The ALJ next found that "the method Inspector Bishop used to verify the [minor]'s age and driver's license [was] sufficient." *Id.* at 11. In making these findings, the ALJ relied on Inspector Bishop's testimony, which the ALJ stated "provides credible and comprehensive overview of his verification of the [minor]'s age and driver's license during the December 1, 2016 inspection." *Id.* at 10 (citing Bishop Decl., CTP Ex. 21, Dkt. No. 7v ¶¶ 9-10); *see also* Narrative Report, CTP Ex. 17, Dkt. No. 7r ¶¶ 5-6 and 9.

⁴ Fed. R. Evid. 602, titled "Need for Personal Knowledge," states in pertinent part that "[a] witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter."

Relying further on Inspector Bishop's testimony, the ALJ found "an abundance of evidence" to support the Complaint allegation that on December 1, 2016 Respondent violated 21 C.F.R. § 1140.14(a)(1) by selling tobacco products to a minor. *Id.* at 12. Based on this finding and on Respondent's admission to violations in the prior CMP actions, the ALJ found that "Respondent committed a total of five repeated violations of FDA's tobacco regulations over a 36-month period . . ." *Id.* at 13. After taking into account the factors listed in 21 U.S.C. § 333(f)(5)(B), as well as additional mitigating factors put forth by Respondent, the ALJ concluded that a "NTSO for a period of 30 consecutive calendar days is a reasonable penalty." *Id.* at 12-15.

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

Before the Board, Respondent does not specifically deny that it did not sell tobacco products to a minor in violation of section 1140.14(a)(1) on December 1, 2016. Respondent's sole assignment of error is that the ALJ improperly admitted the redacted ID into evidence. Again citing the Federal Rules of Evidence, Respondent essentially reprises the arguments in its post-hearing brief objecting to the admission of the redacted ID. *See* Request for Review (RR). In so asserting, Respondent is attempting to establish that, had the ALJ excluded the redacted ID, as Respondent asserts the ALJ should have done because it is unreliable, CTP would not have an evidentiary foundation for citing Respondent for selling tobacco products to a minor on December 1, 2016. We reject this argument as meritless and uphold the ALJ's determination that, on December 1, 2016, Respondent sold tobacco products to a minor, thus establishing the fifth repeated violation of section 1140.14(a) requirements within the 36-month period that included the period from November 8, 2014 to December 1, 2016, and, consequently, a basis for the 30-day NTSO.

The regulations in 21 C.F.R. Part 17 generally prescribe evidentiary rules for the ALJ. *See, e.g.,* 21 C.F.R. §§ 17.37, 17.39. The Part 17 regulations governing the admissibility of evidence, found at 21 C.F.R. § 17.39, require an ALJ to exclude evidence if it is "not relevant or material." 21 C.F.R. § 17.39(c). However, the Part 17 regulations otherwise afford an ALJ considerable discretionary authority over the admission or exclusion of evidence. An ALJ may, for instance, determine whether to apply the Federal Rules of Evidence, and may exclude evidence – even if relevant – if it is subject to a privilege under Federal law or for other reasons. *See, e.g., id.* § 17.39(b), (d), (e), (g).

The ALJ considered Respondent’s objection but decided to admit the redacted ID under section 17.39(c) as “relevant and reliable” evidence. ALJ Decision at 9 (“I am only required to exclude evidence that is not relevant or material to the issues before me I find that the redacted driver’s license . . . is relevant and reliable”). The regulations also permit an ALJ to exclude relevant evidence “if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.” 21 C.F.R. § 17.39(d). After considering this regulation, the ALJ determined that the redacted ID has considerable probative value on the question of whether Respondent sold tobacco products to a minor. ALJ Decision at 9 (“[T]he probative value of the redacted driver’s license . . . is not substantially outweighed by the danger of unfair prejudice or confusion of the issues.”).

Respondent does not argue that the ALJ erred or abused his discretion to the extent he relied on sections 17.39(c) and (d) in making his admissibility determination. Rather, Respondent argues that the ALJ “erred” in admitting the redacted ID even though CTP did not lay a proper “foundation” to have the redacted ID admitted. According to Respondent, CTP failed to establish that the ID belonged to the minor and was the same ID presented to Respondent’s cashier. Respondent also asserts that CTP relied on hearsay in the form of Inspector Bishop’s testimony, but failed to identify any applicable hearsay exception under the Federal Rules of Evidence. RR at 3-4 (citing Fed. R. Evid. Rules 602 and 803).

We disagree with Respondent’s contentions. Respondent relies on the Federal Rules of Evidence,⁵ but the Part 17 regulations do not compel the ALJ, or the Board, to apply the Federal Rules of Evidence in this proceeding (though they do permit such application “when appropriate” such as when the evidence is “unreliable”). See 21 C.F.R. § 17.39(b); see also *Three Star Market*, DAB No. 2906, at 7 n.4 (2018) (“The ALJ and the Board are not bound by the [Federal Rules of Evidence], but may apply the [Federal Rules of Evidence] when appropriate”) (citing *J. Peaceful, L.C. d/b/a Town Market*, DAB No. 2742, at 10 n.7 (2016) (“[T]he rules governing this proceeding provide that the ALJ is not bound by the [Federal Rules of Evidence].”). Accordingly, the ALJ was not required to follow Rule 602; nor was he required to exclude hearsay evidence; nor was his determination to admit any hearsay evidence dependent on whether he found that one or more of the Rule 803 hearsay exceptions applied.

⁵ Respondent relies on the Federal Rules of Evidence to argue that Inspector Bishop lacks the personal knowledge required to “introduce” the redacted ID (RR at 3 (citing Fed. R. Evid. 602)), and to argue that the redacted ID does not fall within the exceptions to the rule against hearsay (*id.* (citing Fed. R. Evid. 803)), but does not rely on the rule for authenticating an item of evidence, found at Fed. R. Evid. 901. In any case, the Federal Rules of Evidence, as stated above, are not required to be applied in this case.

Moreover, we find no error or abuse of discretion in the ALJ's determination that CTP laid sufficient foundation for admitting the redacted ID. The ALJ found highly credible and reliable the inspector's testimony and protocol as establishing that the minor was indeed underage and carrying only an ID that showed that fact. Inspector Bishop testified that the redacted ID is "[a] true and accurate redacted copy" of the minor's ID. CTP Ex. 21, at 3; Hearing Transcript at 19. Respondent challenges this testimony by arguing that Inspector Bishop lacked the personal knowledge necessary to "introduce" the redacted ID. RR at 3; *see also* Hearing Transcript at 8 (Respondent arguing that the "[t]he proper way of introducing a driver's license . . . would be to have the person either testify that yes, this is my license, and I'm [the minor], or the minor's narrative report, which is not being offered as evidence in this case"). Specifically, Respondent argues that Inspector Bishop did not see the ID presented to its cashier during the December 1, 2016 inspection, and did not have knowledge about the ID's chain of custody from the minor to CTP. RR at 3. Respondent, however, ignores that Inspector Bishop indeed has personal knowledge of the ID and how it matches the redacted ID introduced into the evidentiary record of this case. Inspector Bishop testified that the protocol for confirming the age and ID of an undercover minor is for the minor to provide the inspector a physical ID at the beginning of the day. Hearing Transcript at 17. Inspector Bishop testified that minors "have to take [the ID] out, and we observe the ID through physical[ly] . . . holding the ID, and we make sure everything is correct for that minor." *Id.* Inspector Bishop also testified that, consistent with this protocol, *prior to* the December 1, 2016 inspection, he "confirmed that [the minor] was under the age of 18 and possessed her true and accurate identification, showing [that] her birthdate" established that she would in fact be a minor on the inspection date. CTP Ex. 21, at 2-3. Inspector Bishop further testified that the date of birth shown on the redacted ID matches the date of birth on the ID provided by the minor. CTP Ex. 21, at 2; Hearing Transcript at 14. Further, he observed the minor showing ID while making the transaction, although too quickly to confirm that it was indeed the identical one in the record. Hearing Transcript at 12. Thus, Inspector Bishop was able to testify, based on his personal observations, that the relevant information on the redacted ID (the minor's date of birth) was consistent with the information on the ID presented by the minor.

Respondent argues that "[t]he attempt by Mr. Bishop to introduce the redacted [ID] . . . is classic hearsay." RR at 3. Respondent does not identify exactly which statements constitute hearsay, but Respondent presumably objects to Inspector Bishop's statement in his written declaration that the ID showed the minor individual's date of birth.⁶ This statement is the predicate for Inspector Bishop's testimony that the redacted ID is "[a]

⁶ In any case, hearsay is not inadmissible in these proceedings. *See J. Peaceful* at 10 n.7 ("[A]s the Board has long observed, hearsay is admissible in administrative proceedings generally and can be probative on the issue of the truth of the matter asserted, where sufficient indicia of reliability are present."); *see also id.* ("The question facing an ALJ presented with hearsay evidence is not whether it is admissible, but what weight it should be accorded.") (citing *Gateway Nursing Ctr.*, DAB No. 2283, at 6 (2009)).

true and accurate redacted copy” of the minor’s ID based on the matching birthdates. Respondent, however, again disregards that Inspector Bishop’s testimony established that the individual in question was under the age of 18 on December 1, 2016. Inspector Bishop testified that in order to participate in an undercover buy inspection, all minors must be 16 or 17 years of age, and present a valid form of identification. CTP Ex. 21, at 2. Inspector Bishop further testified that prior to entering Respondent’s establishment, he confirmed that the minor was under the age of 18 by checking the date of birth on the minor’s ID. *Id.* at 2-3. Importantly, Inspector Bishop also testified that *he personally observed that particular minor individual purchasing tobacco products at Respondent’s establishment on December 1, 2016.* CTP Ex. 21, at 3; Hearing Transcript at 12. Thus, there is substantial evidence in the record supporting the ALJ’s determination that Respondent violated section 1140.14(a)(1) on December 1, 2016, by selling tobacco products to a minor.

Conclusion

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

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Susan S. Yim
Presiding Board Member