Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Mahin Oil Co., d/b/a Valero
Docket No. A-16-107
Decision No. 2747
November 1, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

The Center for Tobacco Products (CTP) of the U.S. Food and Drug Administration (FDA) sought to impose a civil monetary penalty (CMP) in the amount of $5,000 on Respondent Mahin Oil Company, d/b/a Valero (Mahin, Respondent) for five violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq*. In a decision entering default judgment, an Administrative Law Judge (ALJ) agreed that Mahin violated the Act, but concluded that the sanction imposed should be reduced to a CMP of $500 based on his determination that there were only three violations. Order of Default Judgment and Initial Decision in *Mahin Oil Co., d/b/a Valero*, Docket No. FDA-2016-H-0294, at 1 (2016) (ALJ Decision). On July 6, 2016, CTP filed a motion asking the ALJ to reconsider the ALJ Decision in light of the Board's June 30, 2016 decision in *Orton Motor Company, d/b/a Orton's Bagley*, DAB No. 2717 (2016). In *Orton Motor*, the Board determined that CTP's method of counting violations is based on a reasonable and permissible interpretation of the Act and regulations and is consistent with FDA's published guidance. On July 7, 2016, the ALJ dismissed CTP's reconsideration request. CTP timely appealed the ALJ Decision to the Board.[1]

CTP asks the Board to reverse the ALJ Decision "except its findings that Respondent is liable for selling tobacco products to a minor and failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth" on three dates (November 10, 2014, February 27, 2015, and October 15, 2015), and to reinstate the $5,000 CMP "based on five of Respondent's violations in a 36-month period." CTP Br. at 5-6, citing 21 C.F.R. §§ 1140.14(a) and (b)(1).

[1] The appeal was timely based on the Board's July 7, 2016 order extending CTP's deadline to file a notice of appeal until thirty days after the ALJ ruled on CTP's motion for reconsideration. CTP's brief notes that CTP believes the ALJ erred in dismissing its reconsideration request, but CTP does not ask the Board to review the ALJ's dismissal for error. Accordingly, we proceed to the merits of CTP's appeal.

For the reasons stated below, we conclude that the ALJ's rationale for finding only three violations from November 10, 2014, through October 15, 2015, and reducing the CMP to $500 is legally erroneous. We conclude that CTP's determination to impose the CMP of $5,000 is supported by a reasonable and permissible published interpretation of the governing statutes and regulations. We therefore reverse the ALJ Decision in part as to the legal analysis; we do not disturb the ALJ's factual findings; and we reinstate a $5,000 CMP.

Applicable legal authorities

Section 906(d)(1) of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), authorizes the FDA to regulate the sale of tobacco products, "if the Secretary determines that such regulation would be appropriate for the protection of the public health" and to "impose restrictions on the advertising and promotion of a tobacco product consistent with and to [the] full extent permitted by the first amendment to the Constitution."

As amended by the TCA, 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." 21 U.S.C. § 331(k). The Act also authorizes the FDA to impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products." *Id*. § 333(f)(9). A tobacco product is "deemed to be misbranded" if it is sold in any state "in violation of regulations" issued under the Act. 21 U.S.C. § 387c(a)(7)(B). The Act directed the Secretary of the Department of Health and Human Services to establish the CTP within the FDA and authorized the Secretary to issue regulations restricting the sale and distribution of tobacco products. 21 U.S.C. §§ 387a(e), 387f(d).

The regulations at 21 C.F.R. Part 1140 provide that each tobacco retailer must ensure that all cigarette and smokeless tobacco sales comply with specific requirements. 21 C.F.R. § 1140.14. Among those requirements:

(a) "No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;"
(b) Retailers 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" except that "[n]o such verification is required for any person over the age of 26;" and
(c) In general, "a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine)."

21 C.F.R. § 1140.14(a), (b)(1), (2), (c). The regulations further state that the failure to comply with "any applicable provision" of Part 1140 "in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded" under the Act. 21 C.F.R. § 1140.1(b).

The Act and the regulations governing FDA CMP proceedings relating to tobacco sales at 21 C.F.R. Part 17, specify the CMP dollar amounts that FDA imposes for violations based on the number of violations and the period of time in which they are committed. During the period at issue, section 17.2 of the regulations set out two parallel CMP schedules, consistent with section 103(q)(2)(A) of the TCA, with lower CMPs assessed against retailers who have an "approved training program." 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The FDA stated in guidance, however, that it would use the lower schedule for all retailers until it has developed regulations establishing training program standards. *Guidance for FDA and Tobacco Retailers – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (Revised)* (June 2014)(hereafter "FDA Guidance"), at 8-9[2]; *Guidance for Industry and FDA Staff, Civil Money Penalties for Tobacco Retailers, Responses to Frequently Asked Questions (Revised)*(June 2014)(hereafter "FDA FAQs"), at 12.[3]

The FDA Guidance also explains how the FDA determines the number of violations for purposes of applying the CMP schedule.

> The first time that FDA finds a violation at a retail outlet, its policy is to send a Warning Letter rather than seeking a CMP. If FDA identifies violation(s) at a retail outlet during a follow-up compliance check or a subsequent inspection at that retail outlet, the Agency generally intends to seek civil money penalties to the extent they are appropriate. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate . . . , the Agency also generally intends to seek a no-tobacco-sale order. . . .

[2] http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm252955.pdf (last visited September 22, 2016). Effective September 9, 2016, the FDA removed the table of maximum CMPs from 21 C.F.R. § 17.2 and cross-referenced a new consolidated table of maximum CMPs "associated with statutory provisions authorizing such penalties for all HHS Agencies" at 45 C.F.R. § 102.3 that HHS issued on September 6, 2016. 81 Fed. Reg. 62,358 (Sept. 9, 2016); 81 Fed. Reg. 61,538, 61,565 (Sept. 6, 2016).

[3] http://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm339438.pdf (last visited September 22, 2016).

> To determine the amount of CMP it will seek, FDA counts violations and consults a charging schedule provided in the Tobacco Control Act. FDA counts only one violation from the first inspection that finds one or more violations at an outlet, regardless of the number of violations that were noted and included in a Warning Letter. **For any subsequent inspections, FDA may count any or all violations and its general policy is to count all of them individually.**

FDA Guidance at 13-14 (emphasis added).

To impose a CMP, CTP serves a complaint on the retailer (the respondent). 21 C.F.R. §§ 17.3, 17.5, 17.7, 17.33. The respondent may pay the penalty or appeal the penalty by requesting a hearing before a "presiding officer" who is "an administrative law judge qualified under 5 U.S.C. 3105." 21 C.F.R. §§ 17.3(c), 17.9(a); 21 U.S.C. § 333(f)(5)(A), (9). The respondent must answer the complaint within 30 days or request, within that period, an extension of time to file the answer. 21 C.F.R. § 17.9.

After it submits an answer, a respondent may engage in settlement discussions with CTP. If the parties agree to settlement, the respondent will pay the amount established under the settlement and the case is concluded. FDA has stated in guidance documents, however, "Even if charges are resolved through a settlement agreement, any violations that occurred will be counted in determining the total number of violations for purposes of subsequent enforcement actions." FDA Guidance at 7; FDA FAQs at 7.

If a respondent does not file a timely answer to CTP's complaint, the ALJ "shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute," the ALJ "shall issue an initial decision within 30 days of the time the answer was due, imposing" the smaller of the maximum CMP provided by law or the amount sought in the complaint. 21 C.F.R. § 17.11(a).[4]

A respondent may appeal the ALJ's decision (which the regulations refer to as the "initial decision") to the DAB, which consists of Board Members (Board) supported by the Appellate Division. 21 C.F.R. §§ 17.45, 17.47. The Board may "decline to review the case, affirm the initial decision or decision granting summary decision (with or without an opinion)," or "reverse the initial decision or decision granting summary decision, or increase, reduce, reverse, or remand any civil money penalty determined" by the ALJ. 21 C.F.R. § 17.47(j).

[4] The respondent may, within 30 days, move to reopen the case on the grounds that "extraordinary circumstances" prevented the respondent from filing a timely answer to the complaint. 21 C.F.R. § 17.11(c). If the respondent makes that showing, the ALJ may withdraw the decision and permit the respondent to answer the complaint; if the ALJ "decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision" entering default judgment against the respondent. 21 C.F.R. § 17.11(d).

Case background

The events underlying this appeal are not in dispute. On November 10, 2014, a Mahin employee (1) sold tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a); and (2) failed to verify the purchaser's age by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14 (b)(1). *Mahin Oil Co. d/b/a Valero*, Dkt. No. C-15-3005, FDA-2015-H-2147, Document No. 1 (First Complaint), ¶ 10; *see also* Administrative Record (AR) 1, ¶ 10. On December 11, 2014, CTP sent Mahin a Warning Letter, notifying it of the two violations that occurred on November 10, 2014, and stating that the failure to correct the violations could result in a CMP, among other things. First Complaint, ¶ 10.

On February 27, 2015, a Mahin employee again (1) sold tobacco products to a minor in violation of 21 C.F.R. §§ 1140.14(a); and (2) failed to verify the purchaser's age by photographic identification, in violation of 21 C.F.R. §1140.14(b)(1). First Complaint, ¶ 1; AR 1, ¶ 10. Consequently, CTP filed an administrative complaint against Mahin on July 6, 2015, seeking a CMP of $500 based on three violations in a 24-month period. First Complaint ¶ 13. CTP calculated the number of violations based on its policy to count only one violation from the inspection preceding a Warning Letter and to count any and all violations in any subsequent inspections when determining the CMP amount.

On July 23, 2015, CTP filed a Notice of Settlement Agreement with respect to the First Complaint, which included an Acknowledgment Form in which Mahin admitted to committing the November 10, 2014 and February 27, 2015 violations. *Mahin Oil Co. d/b/a Valero*, C-15-3005, FDA-2015-H-2147, Document No. 3. The Acknowledgment Form also indicated that Mahin understood that these violations may be counted in determining the total number of violations and assessing the CMP amount for purposes of future enforcement actions. *Id.*

CTP investigators subsequently determined that, on October 15, 2015, a Mahin employee again (1) sold tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a); and (2) failed to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, in violation of 21 C.F.R. § 1140.14(b)(1). AR 1, ¶ 9. On February 5, 2016, CTP filed a second complaint against Respondent, seeking a $5,000 CMP based on five violations in a 36-month period. AR 3.

On February 25, 2016, Respondent filed a request for an extension of time of "at least 60 days" to investigate the alleged violations and file an answer. AR 3. The Respondent did not subsequently file an answer, however, and on May 11, 2016, the presiding ALJ ordered Respondent to show cause by June 3, 2016, why the ALJ "should not declare a

default and decide [the] case in accordance with 21 C.F.R. § 17.11." AR 4. Respondent did not respond to the Order to Show Cause. On June 7, 2016, the ALJ issued a decision entering default judgment against Respondent, concluding that Mahin had committed three violations within a 24-month period and reducing the CMP amount to $500.[5]

As noted above, on July 6, 2016, CTP filed a motion asking the ALJ to reconsider the ALJ Decision in light of the Board's June 30, 2016 decision in *Orton Motor*. On July 7, 2016, the ALJ dismissed CTP's reconsideration request.

CTP timely appealed the ALJ Decision to the Board and served Respondent with a copy of its notice of appeal. The Board issued an acknowledgment of the appeal to the parties, which notified Respondent of its opportunity to submit a response to CTP's appeal. Respondent did not submit a response to CTP's appeal or ask for additional time to do so. The time permitted for Respondent to file a written response has expired. Accordingly, we now proceed to decision.

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. 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

1. Issues on appeal from the ALJ Decision

The ALJ found that on November 10, 2014, February 27, 2015, and October 15, 2015, Respondent (1) sold tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a); and (2) failed to verify the purchaser's age by checking a photographic identification in violation of 21 C.F.R. § 1140.14(b)(1). ALJ Decision at 7-9. These findings are not disputed.

[5] Section 17.9(c) of the regulations provides that if a respondent is unable to file an answer to the complaint within the 30-day time period provided, it shall request an extension of time within which to file an answer; the ALJ may, for good cause shown, grant the respondent up to 30 additional days within which to file an answer. In this case, the ALJ did not issue a ruling on Respondent's February 25, 2016 extension request. The May 11, 2016 Order to Show Cause, however, was issued more than 60 days after Respondent requested the extension and provided Respondent with an additional three-week period to answer the Complaint. Accordingly, we conclude that Respondent was provided ample time within which to submit its answer. We also note that Respondent did not file a motion to reopen the ALJ decision on the grounds that extraordinary circumstances prevented it from filing an answer, as provided under 21 C.F.R. § 17.11. Respondent also does not argue on appeal of the ALJ Decision that it was denied sufficient time within which to file an answer to the complaint.

On appeal, the issues raised are:

(1) How many violations do the undisputed findings establish?
(2) What amount of CMP may CTP impose?

2. The ALJ erred in rejecting CTP's method of counting violations.

The ALJ determined that in an administrative action to impose a CMP against a tobacco product retailer, to "define the 'violation,' … is to define the 'unit of prosecution,' and accordingly" to determine the amount of the penalty. ALJ Decision at 2. The ALJ applied various criminal law concepts, including the "rule of lenity" and "multiplication of charges," to his reading of the Act and regulations to conclude that the "unit of prosecution" is "a misbranded tobacco product." *Id.* at 2-5, citing, inter alia, *United States v. Rentz*, 777 F.3d 1105, 1109 (10th Cir. 2015) (en banc) (firearms prosecution, inquiring about "unit of prosecution"); *United States v. Quiroz*, 55 M.J. 334, 338-39 (C.A.A.F. 2001) (endorsing five-factor test for "unreasonable multiplication" in military criminal setting).[6] "Whether a respondent fails to meet one regulatory criterion, all criteria, or something in between," the ALJ concluded, "the result is the same: a misbranded tobacco product." *Id.* at 5. The ALJ therefore rejected CTP's policy to count distinct violations based on each act that contravenes the regulations: "To say that the 'violation' of a regulation describing a misbranded product is the unit of punishment is to mischaracterize the retailer's culpability under the TCA and unreasonably increase the retailer's punitive exposure." *Id.* at 6. Accordingly, the ALJ determined that in this case, Respondent "committed 3 statutory violations within the course of 24 months" and imposed a CMP "of $500 for these three instances of misbranding . . . ." *Id.* at 8-9.

The ALJ's rationale for rejecting CTP's method of counting violations in this matter is, as CTP asserts, the same rationale that the Board found erroneous in the case of *Orton Motor*. As the Board explained in *Orton Motor*, and we summarize below, a program agency's "interpretation of a statute that it is responsible for implementing and of the regulations that the agency has issued is entitled to deference as long as the interpretation is reasonable and the nonfederal party had timely and adequate notice of that interpretation or did not rely to its detriment on another reasonable interpretation." *Orton Motor* at 6, citing *Blackfeet Tribe*, DAB No. 2675, at 11 (2016), citing *Missouri Dep't of Soc. Servs.*, DAB No. 2184, at 2 (2008). Moreover, deference to an agency's interpretation of a statute and implementing regulations is especially warranted where, as in CTP administrative actions, the agency's interpretation has been consistent and predated the litigation in which the agency is seeking to apply it. *Id.* at 6-7.

[6] For a detailed discussion of the same improper application of such criminal law concepts to remedial administrative actions under the Act, *see* DAB No. 2717, at 21-23.

a. The Act does not unambiguously either prohibit or mandate a method of counting violations.

In order to identify the number of violations committed by a retailer for the purpose of applying the escalating CMP amounts set out in the TCA and regulations, the Board in *Orton Motor* first considered the language of the Act and regulations. The language of the FDA tobacco product sales regulations, the Board noted, is "particularly authoritative" because section 102 of the TCA expressly instructed the FDA to issue the provisions, which the FDA had previously published in a 1996 proposed rule but which the Supreme Court struck down in 2000 as then beyond the FDA's authority. *Id.* at 8, n.3.[7] Thus, the TCA "effectively dictated the content of the regulations." *Id.*

The Board also explained that an effort to discern the meaning of the statute must also take into account the purpose of the legislation. Among the stated objectives of the TCA, the Board noted in particular:

> (1) to provide authority to the [FDA] to regulate tobacco products under the [Act], by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division;
> (2) to ensure that the [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;
> * * * *
> (8) to impose appropriate regulatory controls on the tobacco industry . . .
> (9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases . . . .

Id. at 9-10, citing TCA § 3.

The Board next examined the language of the applicable statutes and regulations, including 21 U.S.C. § 331(k), which 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"; section 333(f)(9), which authorizes the FDA to impose CMPs against "any person who violates a requirement of [the Act] which relates to tobacco products"; section 387c(a)(7)(B), which provides that a tobacco product is

[7] The early rule was published in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44,615–18). The Supreme Court struck down the rule as beyond the FDA's authority under the Act prior to the enactment of the TCA. *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000).

"deemed to be misbranded" if it is sold in any state "in violation of regulations" issued under the Act; and section 1140.1(b) of the regulations, which states that "[t]he failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes . . . renders the product misbranded under the Act." *Id.* at 10.

The Board concluded that the above-quoted provisions of "the statute and regulations provide a context for determining what constitutes an act of misbranding but do not mandate how such acts are to be counted for purposes of calculating the applicable CMP amount." *Orton Motor* at 10-11. The Board rejected the argument that these provisions somehow prohibited CTP from charging a retailer with multiple violations arising from a single inspection or transaction; but did not find that the provisions unambiguously required CTP's method of counting violations either. Accordingly, the Board held that the TCA left CTP with discretion to make that determination so long as its approach was not inconsistent with the statute or regulations. *Id.*

b. FDA reasonably interpreted the Act and regulations.

The Board observed that the FDA has issued "clear public guidance with detailed explanation and examples" to show how it counts violations for purposes of setting the amount of CMP that it will seek against a retailer under 21 C.F.R. Part 1140. *Id.* at 12. Relevant here, the FDA's guidance provides:

> **44. How does FDA determine the amount of CMP that it will seek in the complaint for violations of part 1140?**
>
> The first time that FDA finds a violation at a retail outlet, its policy is to send a Warning Letter rather than seeking a CMP. If FDA identifies violation(s) at a retail outlet during a follow-up compliance check or a subsequent inspection at that retail outlet, the Agency generally intends to seek civil money penalties to the extent they are appropriate. . . .
>
> To determine the amount of CMP it will seek, FDA counts violations and consults a charging schedule provided in the Tobacco Control Act.
>
> FDA counts only one violation from the first inspection that finds one or more violations at an outlet, regardless of the number of violations that were noted and included in a Warning Letter. For any subsequent inspections, FDA may count any or all violations and its general policy is to count all of them individually.
>
> Once FDA has counted violations at a retail outlet for the 48-month period that precedes the most recent violation(s), it consults the following charging schedule to determine the amount it will seek in a complaint:

Number of Violations	CMP
1	$0.00 w/ warning letter
2 within a 12-month period	$250
3 within a 24-month period	$500
4 within a 24-month period	$2,000
5 within a 36-month period	$5,000
6 within a 48-month period	$11,000

Thus, if the respondent receives a Warning Letter after the first inspection that notes four violations, and FDA notes two more violations during a follow-up inspection within 24 months, generally FDA would count three of the violations (one for the first inspection and two for the second), and seek $500 under its policy.

To provide another, more detailed, example:

- FDA issued a Warning Letter for selling to a minor (21 CFR 1140.14(a)) and failing to verify photographic identification during an inspection on January 1, 2011. (21 CFR 1140.14(b)).
- A two-part follow-up inspection at the same retail outlet, conducted on June 1 and 7, 2011, observed violations for:
  - selling to a minor;
  - failing to verify photographic identification; and
  - offering free samples of cigarettes (21 CFR 1140.16(d)(1)).
- Thus, FDA has observed five violations at the retail outlet.
- Under its current policy, FDA generally would count four of the violations in determining the amount it will seek: one from the Warning Letter and three from the follow-up inspection.
- Applying these facts to the charging schedule, FDA would seek a CMP of $2,000 in the complaint.

FDA Guidance at 13-15 (footnotes omitted). This guidance shows that each act resulting in misbranding that contravenes a requirement of the regulations is to be considered a distinct "violation" even when that means that more than one violation is cited as having occurred on the same date or as involving a single tobacco product. In addition, the guidance explains that, "if charges [alleged in an initial enforcement action] are resolved through a settlement agreement, any violations that occurred will be counted in determining the total number of violations for purposes of subsequent enforcement actions." *Id.* at 7.

CTP's method of determining the number of violations for purposes of applying the CMP penalty scale, the Board determined, represents an authoritative, permissible interpretation of the Act's requirements that "was published in official public documents as early as June 2014, and republished without change except as to the updated CMP amounts in May 2015." *Orton Motor* at 14. The guidance reflects CTP's reasonable understanding of the Act to plainly bar any "act" that results in a misbranded product. 21 U.S.C. § 331(k). CTP's policy for counting violations thus logically associates "violations" with prohibited acts. As noted, the Act provides that a product will be deemed misbranded if "it is sold or distributed in violation of regulations" prescribed pursuant to the Act. 21 U.S.C. § 387c(a)(7)(B). CTP reasonably reads this provision as incorporating the regulatory prohibitions against particular acts of misbranding as requirements imposed by the statute. *Orton Motor* at 14. As noted in *Orton Motor*, CTP's interpretation is particularly appropriate in light of Congress' express mandate in the TCA for the FDA to reissue the proposed regulations struck down prior to the enactment of the TCA. *Id.* at 15.

Furthermore, the language and structure of the regulations support CTP's understanding that each act of noncompliance with one of the regulatory requirements constitutes a violation of the Act. Section 1140.10 provides generally that each "retailer is responsible for ensuring that the cigarettes . . . it . . . sells, or otherwise holds for sale comply with all applicable requirements under this part." Section 1140.14 then specifies the "additional responsibilities" applicable to retailers as follows:

> (a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;
> (b) (1) Except as otherwise provided in §1140.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall 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;
> (2) No such verification is required for any person over the age of 26;
> (c) Except as otherwise provided in §1140.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine);
> (d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes . . . ; and
> (e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

By setting out five independent "additional responsibilities" with which retailers of tobacco products must comply, the provision can reasonably be read, as CTP does, as identifying five independent requirements. Logically, a retailer may violate more than one requirement during a sale (as Mahin did in selling to a minor and failing to check identification) but need not do so. As the Board stated in *Orton Motor*, treating the failure to comply with each requirement separately does not amount to imposing multiple penalties for a single "act," and each violation may be viewed as an independent act even though they may all be observed simultaneously. *Orton Motor* at 16. Thus, "CTP may rationally determine that those retailers whose acts violate multiple distinct requirements should be subject to increasing penalties in order to encourage more careful compliance with each of the different requirements." *Id.* at 17.

Accordingly, we conclude that the ALJ erred in rejecting CTP's method for counting violations committed by a retailer and instead determining that a retailer has violated the statutory provision against misbranding only once even if it commits multiple prohibited acts and/or fails to perform required acts multiple times.

3. We impose a CMP of $5,000 against Mahin.

Section 17.11(a) of the regulations, "Default upon failure to file an answer," provides that if a respondent does not file an answer to a complaint for which service was properly effected, the ALJ "shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute," shall issue a decision imposing "(1) The maximum amount of penalties provided for by law for the violations alleged; or (2) The amount asked for in the complaint, whichever amount is smaller."

In this case, the ALJ found that Mahin received CTP's February 1, 2016 complaint as of February 24, 2016, and that Mahin failed to file a timely answer to the complaint. ALJ Decision at 1, 7. Accordingly, the ALJ accepted as true the allegations in the complaint that on November 10, 2014, February 27, 2015, and October 15, 2015, Mahin employees: 1) sold tobacco products to a minor in violation of 21 C.F.R. § 1140.14(a); and 2) failed to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth in violation of 21 C.F.R. § 1140.14(b)(1). ALJ Decision at 8-9.

CTP argues on appeal that, "[u]nder the Orton Motor precedent, the maximum amount of penalty provided for by law for Respondent's violations is $11,000, because Respondent committed six violations in a 23-month period." CTP Br. at 8. CTP states, however, that the complaint "only sought a $5,000" CMP. CTP Br. at 8. "Because the [CMP] sought … is less than the maximum amount provided by law," CTP asserts, "the ALJ erred in not imposing the $5,000 [CMP] sought by CTP in the Complaint." CTP Br. at 8.

In light of our conclusion that CTP's method of determining the number of violations for purposes of applying the CMP penalty scale is based on a reasonable and permissible interpretation of the statute and regulations, we conclude that CTP was authorized to impose a CMP against Respondent "in the amount of $5,000 … for five violations within a thirty-six month period," as it requested in the February 1, 2016 complaint. AR 1, ¶ 14. We need not address CTP's argument that the "maximum amount of penalties provided for by law for the violations alleged" in this case is $11,000 because that amount exceeds the amount requested in CTP's complaint. Accordingly, we conclude that the ALJ erred in reducing the CMP to $500 based on his determination that there were only three violations, and we impose a CMP of $5,000 against Mahin.

Conclusion

For the reasons explained above, we reverse the ALJ Decision and impose a CMP of $5,000 based on CTP's February 5, 2016 complaint against Respondent, counting five violations in a 36-month period.

/s/
Christopher S. Randolph

/s/
Susan S. Yim

/s/
Leslie A. Sussan
Presiding Board Member