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

Orton Motor Co., d/b/a Orton's Bagley
Docket No. A-16-56
Decision No. 2717
June 30, 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 $500 on Respondent Orton Motor Company, d/b/a Orton's Bagley (Orton, Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq. In a decision issued on February 8, 2016, the ALJ agreed that Orton violated the Act, but concluded that the sanction imposed should be reduced to a CMP of $0 and a "judicial Warning Letter." Initial Decision and Order in *Orton Motor Co., d/b/a Orton's Bagley*, Docket No. FDA-2015-H-3414, at 1 (2016) (ALJ Decision).[1] CTP timely appealed the ALJ Decision. CTP asks the Board to reverse it "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 two occasions (May 16, 2015, and July 10, 2013), and to reinstate the $500 CMP "for three violations of FDA's tobacco regulations in a [24]-month period." CTP Br. at 30, citing 21 C.F.R. § 1120.14(a) and (b)(1).

For the reasons explained below, we conclude that the ALJ's rationale for finding only one violation and reducing the CMP to $0 is legally erroneous. We conclude that CTP's determination to impose the original CMP is supported by a reasonable and permissible published interpretation of the governing statute 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 $500 CMP.

## Applicable legal authorities

The Act, as amended by the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), 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

[1] Documents in the administrative record indicate that Respondent's title is "Orton Motor, Inc." The ALJ Decision uses the title "Orton Motor Company," however, and we use that title to maintain consistency on review.

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, among other things, provide that each retailer must ensure that all cigarette and smokeless tobacco sales comply with specified 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 term "misbranded" may seem an odd fit for activities like sales to minors that do not involve tampering with the content or labelling of tobacco products, but Congress chose in the TCA to graft FDA's role in tobacco regulation onto the existing mechanisms and terminology used for food and drug regulation. Section 906(d)(1) of the TCA explained that the FDA was authorized 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." The Secretary is to make that determination "with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account"–

> (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

The Act and the regulations governing FDA CMP hearings at 21 C.F.R. Part 17, specify in dollar amounts the CMPs that FDA imposes for violations based on the number of violations and the period of time in which they are committed. Section 103(q)(2)(A) of the TCA and section 17.2 of the regulations set out two parallel CMP schedules, with lower CMPs assessed against a retailer who has an "approved training program." 21 U.S.C. § 333 note; 21 C.F.R. § 17.2. The FDA has stated in CMP guidance documents, however, that it will use the lower schedule for all retailers until it has developed regulations establishing standards for training programs. Guidance for Industry and FDA Staff – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions at 13 (May 2015) (FDA Guidance), http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf; *see also* Guidance for FDA and Tobacco Retailers – Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers at 8-9 (June 2014), http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf.

The FDA Guidance also explains generally how the FDA determines the number of violations for purposes of applying the statutory/regulatory 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. . . .
>
> 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).

The CMP hearing regulations permit a retailer to appeal a CMP by requesting a hearing before a "presiding officer" who is a qualified ALJ. 21 C.F.R. §§ 17.3(c), 17.9(a). The regulations permit CTP or any respondent to appeal an initial ALJ decision to the Board, as the entity designated by the FDA Commissioner to hear appeals. *Id*. § 17.47(a).

## Case background

The events from which this case arose are not in dispute. On July 10, 2013, an Orton employee sold tobacco products to a minor and failed to verify the purchaser's age by photographic identification before the sale. Administrative Record (AR) 1 (CTP Complaint) at 3. Based on this transaction, CTP issued a Warning Letter to Orton dated August 15, 2013 reporting two violations and advising that any further violations could result in the imposition of a CMP. *Id.* On May 16, 2015, an FDA inspector conducting an undercover investigation observed an Orton employee again sell tobacco products to a minor and again fail to obtain photographic identification. *Id.* CTP then filed a Complaint against Orton seeking a CMP of $500 reflecting three violations within 24 months.

In answer to the CTP Complaint, Orton argued that the Act and implementing regulations do not authorize CTP to cite multiple violations arising out of one transaction; that therefore a $500 CMP is improper here, because two of the three violations arose from one transaction; and that CTP procedures in this matter failed to provide required notice and otherwise violated due process. AR 3 (Answer) at 3-4.

The ALJ sought and received legal briefing on these questions but denied oral argument as unnecessary. ALJ Decision at 1. Both parties moved for summary judgment, and Orton stipulated as to the facts. The ALJ proceeded to issue his Initial Decision, from which CTP now appeals.

## Standard of review

Under the applicable regulations, 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

In this appeal, the facts that Respondent sold tobacco products to a minor on two occasions, and that on neither of those occasions did Respondent's employees verify the purchaser's age by checking identification, are undisputed. It is also not disputed that such sales violated the Act and the FDA regulations. The salient issues are two legal questions:

(1) How many violations do these facts establish?
(2) What remedies may CTP impose?

As to the first question, the ALJ concluded, after a wide-ranging excursion into various unrelated and inapplicable criminal law concepts concerning the application of a "rule of lenity" and the "multiplication of charges" based on his definition of a "unit of prosecution," that the existence of a violation should be determined by a "misbranded tobacco product" rather a violation of a statutory (or regulatory) requirement. ALJ Decision at 3-4, citing, inter alia, *United States v. Rentz*, 777 F.3d 1105, 1109 (10th Cir. 2015) (en banc) (firearms prosecution, inquiring about "unit of prosecution") and *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). He then suggested that, since any violation of a regulatory restriction on tobacco sales suffices to render a tobacco product "misbranded," it follows that only one violation may be found in a particular sales event, since the misbranding is "the test," and the reason why it is misbranded "is not, at least as far as the 'unit of prosecution' is concerned." ALJ Decision at 5.

As to the applicable remedy, the ALJ notes that the FDA currently limits the penalties available (as relevant here), to a warning letter for the first occasion, a $250 CMP for the second violation within 12 months, and a $500 CMP for the third violation within 24 months). ALJ Decision at 6; 21 C.F.R. § 17.2. Based on his reasoning about liability, the ALJ concluded that two "cases of misbranding" had occurred within 22 months, but nevertheless imposed no CMP. *Id*. He explained that, in his view, "this is the first instance in which the Respondent has received the process required by statute," evidently referring to the filing of the complaint and proceeding before the ALJ. *Id*. at 7. He therefore considered it "unnecessary" to address "the legal efficacy of the 'Warning Letter'" referenced in the FDA Complaint as served after the initial violation. *Id*. at 6. It is not entirely clear what the ALJ meant by this phrase, but it appears that the ALJ decided that he need not consider whether the Warning Letter proved an earlier violation in light of the fact that no appeal process was provided at the time of the warning. Based on this analysis, the ALJ decided that "the only permissible sanction" for the "allegations which are the subject of this summary decision" is a $0 CMP and a Warning Letter, the latter of which the ALJ himself issued and appended to his decision. *Id*. at 7.

CTP argues that the Act unambiguously requires it to count "the number of regulations with which a retailer failed to comply over a certain period of time" in order to determine the penalty to impose for violations of the Act. CTP Br. at 3 (emphasis omitted). CTP further argues that, even were the Act considered ambiguous about how to determine the number of violations, CTP's interpretation that each breach of a regulatory requirement is a violation is entitled to deference because "it was reasonable and permissible and the public had notice of such interpretation since at least December 2013." *Id.*

CTP further contends that the ALJ's handling of the penalty question reflects his misunderstanding about the process initiated by the FDA Complaint. CTP Br. at 5 nn.7, 8. CTP explains that the Warning Letter was not proffered as evidence of the violations on the earlier date, which the CTP avers it stood ready to prove by evidence had the

Respondent not admitted the facts. *Id*. at 5 n.7. CTP asserts that the present proceeding permitted the Respondent its statutory opportunity for a hearing on the violations alleged as to the earlier date and that no such process is required prior to the issuance of a warning letter (which is not a sanction but rather an "advisory action"). *Id*. at 5 n.8.

As noted, the issues before us are entirely legal questions, which we review for simple error. 21 C.F.R. § 17.47(k). As an administrative adjudicative body, in conducting our review, we are bound by all applicable laws and regulations. Where the applicable law is clear, we apply it by its terms. When it is silent or ambiguous, we must determine how to appropriately interpret and apply it. We do not undertake to develop our own interpretation in a vacuum, however. 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. *Blackfeet Tribe*, DAB No. 2675, at 11 (2016), citing *Missouri Dep't of Soc. Servs.*, DAB No. 2184, at 2 (2008). Deference to an agency interpretation is especially appropriate where the interpretation has been a consistent one predating the litigation in which the agency is seeking to apply it.

Orton argues that the FDA Guidance is not entitled to such deference for its interpretations of the governing statutes and regulations because the guidance was not issued in a formal regulation having the force of law. Orton Br. at 24-25, citing *Wos v. E.M.A.*, 133 S. Ct. 1391, 1402 (2013), relying in turn on *Christensen v. Harris Cnty*., 529 U.S. 576, 587 (2000); distinguishing *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The question of the degree of deference which courts accord to various agency pronouncements concerning the meaning of applicable statutes and regulations is certainly a complex and evolving area of law, but it need not long detain us here. First, we sit as part of the administrative adjudication process, not as a federal court. While the various court approaches to reviewing agency action inform our thinking, they do not directly apply to our role. Our decision becomes the final agency action on behalf of the Secretary and is then subject to court review. As agency adjudicators, we consider the substantive expertise and enforcement experience of the program agency as factors in determining what deference to accord to particular interpretations. Our decisions are issued based on adversarial proceedings resulting in

findings of fact and conclusions of law.[2] Second, the interpretations at issue here relate to both the statute and the implementing regulations, both of which discuss CMPs for misbranding tobacco products through violations of particular requirements and neither of which expressly addresses how to count the number of individual violations in relation to the applicable CMP amount. In *Christensen*, the Court recognized its prior holdings that an agency's interpretation of its own regulations should be given deference when the regulation is ambiguous, but found that, in the case before it, the regulation was not ambiguous but "plainly permissive," so that an opinion letter by the agency to the contrary could not overcome "the regulation's obvious meaning." 529 U.S. at 588, citing *Auer v. Robbins*, 519 U.S. 452 (1997); *see also Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945). We find no such obvious meaning in either the statute or regulations relating to the question before us. It is therefore appropriate to consider whether the FDA Guidance, and CTP's actions here, reflect reasonable and permissible interpretations of the applicable law.

We thus focus our analysis consistent with these principles, and then explain briefly why we find the ALJ's rationale, and in particular his importation of inapplicable criminal law principles, erroneous. Finally, we explain why the original CMP amount is appropriate and the ALJ's purported Judicial Warning Letter is without effect.

**2. CTP's method of counting violations is not inconsistent with the Act or regulations.**

a. <u>We look to the language and intent of the TCA to interpret its applicable provisions.</u>

[2] In this regard, our decision evaluating the applicability of the FDA Guidance is unlike the rulings of the Department of Labor Administrator discussed in *Skidmore*. *Skidmore v. Swift & Co*., 323 U.S. 134 (1944). We do not treat the FDA Guidance as binding authority but we do find that FDA's guidance, like that of the Administrator in *Skidmore*, is "made in pursuance of official duty, based upon more specialized experience and broader investigations and information than is likely to come to a judge in a particular case" and does "determine the policy which will guide . . . enforcement. . . ." *Id*. at 139-140. At a minimum, the FDA's issuances too "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance [and the] weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id*. at 140; *see also Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 149 (1991) ("It is well established 'that an agency's construction of its own regulations is entitled to substantial deference.'"); *id*. at 150 ("In situations in which 'the meaning of [regulatory] language is not free from doubt,' the reviewing court should give effect to the agency's interpretation so long as it is 'reasonable' . . . ."); and *id*. at 151 ("Because applying an agency's regulation to complex or changing circumstances calls upon the agency's unique expertise and policymaking prerogatives, we presume that the power authoritatively to interpret its own regulations is a component of the agency's delegated lawmaking powers.") (case citations omitted from each quotation). Ultimately, we would not reach a decision different than we do here even were we applying *Skidmore* deference.

The determination of how to identify the number of violations that have occurred for purposes of applying the scheme of escalating CMP amounts must begin with the language of the Act, and with the regulations implementing the Act's provisions. We note that, in a rather unusual situation, section 102 of the TCA expressly instructed the FDA to reissue a regulation "identical in its provisions to part 897 of the regulations promulgated . . . in the August 28, 1996, issue of the Federal Register (61 Fed. Reg. 44615–44618)," with specific exceptions.[3] FDA did so by final rule promulgating 21 C.F.R. Part 1140. 75 Fed. Reg. 13,225 (March 19, 2010) (entitled "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents"). The fact that the statute thus effectively dictated the content of the regulations means that the regulations are particularly authoritative in their implementation of the statute's language and intent.

Any effort to discern the meaning of a statute must also take into account its intended purposes. Both the ALJ and the Respondent acknowledge that the reasonableness of an interpretation of a statute should be informed by consideration of the overall goals and purpose of the statute. ALJ Decision at 2; Orton Br. at 8. The ALJ focused, however, on a single aspect of the stated purpose of the TCA, i.e., "to maintain the right of adults to purchase tobacco products while at the same time ensuring they are not sold or accessible to underage purchasers." ALJ Decision at 2, citing TCA § 3(7). This focus overlooks the 49 congressional findings and 10 express purposes laid out in sections 2 and 3 of the TCA. A much broader understanding of the intended effects of the TCA in relation to retail sales and public health arises from a fuller review of those sections. Among the congressional findings, for example, we note the following in particular:

> (1) The use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults.
> (2) A consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.
> (3) Nicotine is an addictive drug.

[3] The earlier regulations had been stricken down by the Supreme Court 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). We note that the statute did not adopt the preamble of the earlier final regulations, and the authority for the reissued regulations had changed sufficiently that much of the preamble is no longer relevant. Nevertheless, some of the explanations in the preamble to the original proposed rule remain useful in understanding the terms of the current rule. In particular, in relation to our review of ALJ decisions involving interpretations of applicable law, the regulatory language in section 17.47(k) is unchanged and the preamble explained that the ALJ will "serve as the fact finder" and Board's role will "be similar to that of an appellate court." 60 Fed. Reg. 38,612, at 38,623. Moreover, the Board's legal interpretations represent the final decision of the Secretary of the Department of Health and Human Services. 60 Fed. Reg. 38,612, at 38,614 ("DAB's decision will constitute final agency action on contested FDA civil money penalties matters").

> (4) Virtually all new users of tobacco products are under the minimum legal age to purchase such products. . . .
>
> * * * *
>
> (12) It is in the public interest for Congress to enact legislation that provides the [FDA] with the authority to regulate tobacco products and the advertising and promotion of such products. The benefits to the American people from enacting such legislation would be significant in human and economic terms.
>
> (13) Tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.
>
> (14) Reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. . . .
>
> * * * *
>
> (29) It is in the public interest for Congress to adopt legislation to address the public health crisis created by actions of the tobacco industry.
>
> (30) The final regulations promulgated by the Secretary of Health and Human Services in the August 28, 1996, issue of the Federal Register . . . are consistent with the first amendment to the United States Constitution and with the standards set forth in the amendments made by this subtitle for the regulation of tobacco products by the [FDA], and the restriction on the sale and distribution of, including access to and the advertising and promotion of, tobacco products contained in such regulations are substantially related to accomplishing the public health goals of this division.
>
> (31) The regulations described in paragraph (30) will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. . . .

TCA § 2. Among the additional purposes set out for the TCA, we note particularly the following:

> (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 . . . .

TCA § 3. Our review of the parties' contentions about how the requirements for retailers concerning tobacco sales are to be understood and applied will be informed by this picture of Congress' intent.

The Act authorizes CTP, as its brief puts it, to seek a CMP "against 'any person who *violates a requirement of th[e] Act* which relates to tobacco products'" and "deems a tobacco product to be misbranded if its sale or distribution does not comply with the regulations . . . ." CTP Br. at 15, quoting 21 U.S.C. § 333(f)(9)(emphasis in brief) and citing 21 U.S.C. § 387c(a)(7)(B) and 21 C.F.R. § 1140.1(b). The statute prohibits the "following acts and the causing thereof" which include "(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the **doing of any other act with respect to,** a food, drug, device, **tobacco product**, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and **results in such article being adulterated or misbranded**." 21 U.S.C.A. § 331 (emphasis added). While relying on these same provisions, the parties reach diametrically opposed understandings of their meaning.

b. <u>The Act does not unambiguously either prohibit or mandate a method of counting violations.</u>

Orton argues that the statute unambiguously **prohibits** CTP from charging a retailer with multiple violations arising from a single inspection or transaction. Orton Br. at 1-2, 7. Orton states that the statutory provisions, taken together –

> (i) prohibit acts that result in a tobacco product being "misbranded," [21 U.S.C.] § 331(k); (ii) partially define which acts by a retailer cause such misbranding, *id*. at § 387c(a)(7); and (iii) delegate authority to the Secretary to further define misbranding through regulations governing retail sales of tobacco products, *id*. § 387f(d).

Orton Br. at 10, also citing 21 C.F.R. § 1140.1(b) ("The 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."). Orton concludes that the plain language of these provisions, read together with section 333 note regarding tobacco retailer CMPs,

somehow demonstrates that CTP lacked statutory authority to determine the amount of a CMP based on more than one regulatory violation at a time. *Id*. at 7, 10. While we agree with Orton that the cited provisions show that "Congress was concerned with and sought to penalize retailers who 'misbranded' tobacco products" (*id*. at 10), we see no prohibition against treating multiple acts of misbranding as violations for CMP purposes regardless of whether they occurred in the course of one or many inspections or transactions. Nor do we see any indication in the language of the cited provision that a particular tobacco product may only be considered to be misbranded one time no matter how many different non-compliant acts occur in the course of its distribution or sale.

Indeed, CTP makes the compelling point that Congress demonstrated in the penalty section of the Act that it knew how to limit the number of violations for multiple acts in the course of one transaction when it wanted to do so. CTP Reply Br. at 5. The CMP provisions for unlawful distribution of drug samples at 21 U.S.C. § 333(b)(2) specifically provide that, for purposes of that paragraph, "multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation." Since Congress chose not to include any similar provision in relation to tobacco retailer violations arising out of the same transaction or inspection, we cannot agree with Orton that the statute unambiguously restricts CTP to considering all violative acts during an inspection or transaction as one violation.

CTP, on the other hand, argues that the statute and regulation unambiguously **require** its method of counting violations. CTP Br. at 15. CTP argues that the plain language of the Act prohibits any act that causes a tobacco product to become misbranded, and that therefore a CMP may thus be assessed "for each such misbranding violation" as defined by the regulations. CTP Br. at 15-16. We disagree that the language on which CTP relies is unambiguous. The statutory language is sufficiently broad that we would have considered some alternative interpretations by CTP permissible, which in itself demonstrates ambiguity. In our view, 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, thereby leaving CTP with discretion to make those determinations so long as its approach is not inconsistent with the statute or regulations.

We thus do not find that the Act provides definitive authority as to whether multiple acts of misbranding may be found to have occurred with regard to a single tobacco product or during a single sale or inspection. The only express limitation on how penalties may be applied when multiple violations have occurred appears in the provision for CMPs for "violation of tobacco product requirements" which states that "any person who violates a requirement of this chapter which relates to tobacco products shall be liable [for a CMP] in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000

for all such violations adjudicated in a single proceeding." 21 U.S.C.A. § 333(f)(9)(A).[4] The Act thus limits the CMP which may be imposed "in a single proceeding," no matter how many violations may be found in that adjudication. Yet Congress did not choose to spell out how many violations might be found or counted during a single inspection or might arise from a single transaction.

We therefore look to whether the program agency responsible for implementing these provisions of the Act and regulations has provided clear and consistent interpretations of the relevant language. For the reasons explained below, we find the interpretations on which the CTP counting approach is based to be reasonable and permissible.

c. We defer to an agency's published interpretation, if reasonable and permissible.

On the questions before us of how to determine what constitutes a violation and how to count violations for purposes of setting the amount of a CMP, the FDA has indeed issued clear public guidance with detailed explanation and examples as follows:

> **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:

[4] As shown earlier, the Act provides for a sliding scale of CMPs for retail sale violations that all fall well below these caps. 21 U.S.C. § 333 note.

| 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 [5] |

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 implies that considering each act resulting in misbranding contrary to 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.[6]

[5] The same schedule of CMP amounts, increasing based on higher numbers and closer timing of violations, appears in the regulations at 21 C.F.R. § 17.2 implementing the same schedule from the Act as cited earlier.

[6] The latter point is made evident in both examples. In the first example, two violations are noted on a single follow-up inspection; in the second example, three violations are noted during two visits implying that two of them occurred during one of the visits.

The guidance is authoritative, consistent and 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. No evidence has been presented that CTP has ever acted inconsistently with this guidance. While such guidance cannot impose new binding requirements, it may document and provide the public with the agency's informed understanding of the meaning of the requirements that do appear in statutes and regulations within that agency's responsibility, so long as that understanding is consistent with and permissible under the statutory and regulatory provisions and so long as the non-federal party involved had notice of that understanding (or did not rely on another reasonable interpretation). Orton has not denied having been on notice of the FDA's guidance.[7] The remaining question therefore is whether this understanding of a "violation" is permissible, that is, not in conflict with the statute.

To be permissible, the agency's interpretation need not be the only reasonable interpretation, or even the one that we might independently adopt. CTP argues that its interpretation is "wholly consistent with the statutory scheme and legislative intent." CTP Br. at 25. Generally, statutes intending to protect the public health are broadly construed to serve that purpose and the Supreme Court has specifically called for a "liberal construction" of the Act to that end. CTP Br. at 15, quoting *United States v. An Article of Drug …Bacto-Unidisk…*, 394 U.S. 784, 798 (1969).

We agree with CTP that the Act plainly bars any "act" resulting in a misbranded product. 21 U.S.C.A. § 331(k). CTP thus logically associates "violations" with prohibited acts. In contrast, the ALJ's conclusion that the "misbranded tobacco product" itself constitutes the violation, rather than a particular action of misbranding, is misplaced.[8] Put most simply, a product is not an action. Moreover, the Act expressly provides that non-compliance with any regulatory provision issued under the TCA will also constitute misbranding. 21 U.S.C. § 387c(a)(7)(B). CTP reasonably construes this statutory provision as incorporating the regulatory prohibitions against particular acts of

[7] Even were the Respondent unaware of the FDA Guidance, Respondent has made no showing that it could have relied or did in fact rely on an alternative interpretation of how many violations it might be considered to have committed in relation to a particular tobacco product or sale, in the sense that it would somehow have behaved differently had it known how violations would be counted.

[8] For example, the ALJ stated that a "'misbranded tobacco product' is different from something that 'violates a requirement of this chapter which relates to these products.'" ALJ Decision at 3, quoting 21 U.S.C. § 333(f)(9). The ALJ then assumed that "the 'requirements' of the chapter" referred only to express requirements contained within other sections of the TCA (regarding such matters as manufacturer registration or tobacco flavorings), but not to requirements specified in the implementing regulation. *Id.* He reasoned that there was "no 'requirement' that a product *not* be misbranded," but rather "simply consequences for the entity guilty of the misbranding if the product is misbranded." *Id*. (italics in original). This cramped understanding of what constitutes a "requirement" of the TCA is entirely inconsistent with the language, purpose and history of the TCA. A "misbranded tobacco product" is not the "requirement" of the Act; the requirement of the Act is that a tobacco product not be sold or offered for sale by a retailer in a manner non-compliant with applicable requirements including those against misbranding. The consequences to which the ALJ refers ensue precisely because a requirement to comply with the statute and the implementing regulations has been violated in one or more instances.

misbranding as requirements imposed by the statute. This construction is particularly reasonable given that, as explained earlier, Congress consciously adopted the relevant regulatory provisions by ordering their reissuance. We thus conclude that the ALJ erred in determining that the statutory provision against misbranding has been violated only **once** if multiple actions are performed in violation of multiple regulatory requirements.

Although Orton asks us to uphold the ALJ Decision, its brief actually suggests a different so-called "unit of prosecution" than that articulated by the ALJ. Whereas the ALJ defined the unit as a "misbranded tobacco product," Orton proposes that the unit be "a single inspection or transaction" regardless of the number of non-compliant actions observed during the inspection.[9] Orton Br. at 1, 6. Nothing in the Act references events occurring during a single transaction or observed during a single inspection as somehow constituting the measure of an act violating an applicable requirement. The ALJ, however, reasoned that, "[e]ven if one were to take a more expansive view of the language in the TCA authorizing the [CMPs] . . ., the Secretary's phrasing of the regulations mandates" his conclusion that the "unit of prosecution" is the "misbranded tobacco product" and "not the type of misbranding" that determines liability for a CMP. ALJ Decision at 5. We therefore review the regulatory language to determine whether CTP is obliged to treat all violations involving a tobacco product, or occurring during a single inspection or transaction, as a single violation or whether CTP's interpretation that each act contrary to a regulatory requirement counts as a separate violation is permissible.

d. <u>The regulation may permissibly be read as indicating that each act of noncompliance with one of its requirements constitutes a violation of the Act.</u>[10]

Section 1140.10 provides generally (omitting terms relevant to manufacturers or distributors) 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:

[9] The Respondent does not explain this proposed substitution but it is apparent that treating the individual misbranded tobacco product as the "unit of prosecution" would itself present potential enforcement questions such as whether the sale of multiple packs of cigarettes during a single transaction or the presence of multiple packs in a vending machine constituted multiple acts of misbranding and multiple violations. Of course, the alternative proposed by the Respondent is open to other practical questions such as how to view multi-day inspections which may involve multiple observed transactions.

[10] We note that CTP distinguishes between identifying an act as a violation for purposes of determining the appropriate amount of the CMP and identifying the specific threshhold act that triggers liability for the CMP. CTP Br. at 9, n.11, 19. We do not find this distinction useful for our analysis of whether it is permissible for CTP to consider multiple acts affecting a tobacco product during an inspection or transactions as constituting separate violations. We therefore do not address it further.

> In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:
>
> (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.

This provision can reasonably be read, as CTP does, as identifying five independent requirements with which retailers of tobacco products must comply.[11] These requirements essentially consist of not selling to minors; checking identification for all buyers 26 or younger; not selling through vending machines (except as allowed); not breaking open retail packaging for individual sales; and remediating impermissible displays or signage.

As a matter of logic, it is possible to violate more than one requirement during a sale (as Orton admittedly did in selling to a minor and failing to check identification). That does not mean, however, that treating the failure to comply with each requirement separately amounts to imposing multiple penalties for a single "act." Non-compliant sales by vending machine have no necessary relationship to posting non-compliant signage or to single cigarette sales. Each may be viewed as an independent act even though they may

[11] The ALJ's analysis of the regulations was based on the use of the "and" rather than "or" to conjoin the list of requirements which he said implied "an expectation that failing to observe any single one of the responsibilities causes the tobacco product to be misbranded." ALJ Decision at 5. We agree that noncompliance with "any single one" of the requirements constitutes misbranding. It does not logically follow, however, that only one of those acts of misbranding may be cited in relation to a particular tobacco product or a particular investigation of a retailer.

all be observed simultaneously.[12] 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. Such a determination is not inconsistent with the table in the statute providing for increasing CMP amounts for increasing numbers of violations in a specified period of time. 21 U.S.C. § 333 note. As with the statute, nothing in the terms of the regulation explicitly ties the identification or "counting" of violations to either the number of transactions in which they took place or the number of inspections during which they were observed.

Orton makes several arguments, however, for its position that CTP could not properly consider more than one violation from each inspection in determining the applicable CMP amount. We address these arguments next.

e. <u>The Act does not distinguish retailers from manufacturers with respect to citing multiple violations per inspection</u>.

Orton acknowledges the language of the Act, cited earlier, imposing a maximum penalty for "violation of tobacco product requirements" at $1,000,000 "for all such violations adjudicated in a single proceeding." Orton Br. at 18, citingTCA § 103(c). Orton suggests, however, that this provision shows that liability for multiple violations at one time was contemplated only for manufacturers but not for retailers of tobacco products. Orton Br. at 19 ("Had Congress intended to assess multiple violations for one transaction in a single inspection, it could have implemented language that mirrors the manufacturer-directed penalty scheme.").

Orton provides no basis for its assumption that section 333(f)(9)(A) applies only to manufacturers. To the contrary, the section applies by its own terms to "any person who violates a requirement of this chapter." Such persons would include those who violate section 331(k) by committing acts of misbranding as defined in the regulations issued under section 387f(d).

It is true, as Orton points out at length, that the legislative history reflects legislative awareness of retailers' concerns and changes made in the drafting of the statute as a result. Orton Br. at 20-23, and citations therein. Primary among those changes was the inclusion of a much lower scale of CMP amounts restricting penalties for retailers below

[12] The independence of these requirements may be less obvious in relation to the acts here in which the retailer sold cigarettes to a minor and failed to check that person's identification. However, the fact that both acts were committed in the course of one sale in a particular case does not imply a necessary dependence. A retailer might, for example, fail to check the identification of a person 26 or younger before making a sale, and thus misbrand the tobacco product sold, without having made a sale to a minor (if the purchaser were over 18). CTP could thus rationally consider the act of completing the sale even though the purchaser was less than 18 years old to be an additional violation justifying greater liability.

even the cap provided for all persons in section 333(f)(9)(A).[13] 21 U.S.C. § 333 note. Nothing in section 333 note, and nothing Orton identifies elsewhere in the statute,[14] however, removes retailers from the application of section 333(f)(9)(A). To the extent that Orton recognizes that section 333(f)(9)(A) permits recognition of multiple violations from a single transaction and their adjudication in a single proceeding, that same reasoning supports CTP's authority to proceed as it has here.

e. The Act does not require that retailers have notice of each violation before a second violation may be cited and considered in setting the CMP amount.

Orton argues that notice and process requirements in the TCA imply that CTP is restricted to "charging one violation per transaction or inspection." Orton Br. at 15, citing TCA §§ 103(q)(2)(A)(i) (spelling out the graduated scale of CMP amounts) and 103(q)(1)(B)-(E). Section 103(q)(1) of the TCA provides that FDA "shall issue guidance—

* * * *

> (B) providing 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 . . . ;
> (C) providing for a hearing pursuant to the procedures established through regulations of the [FDA] for assessing [CMPs] . . . ;
> (D) providing that a person may not be charged with a violation at a particular retail outlet unless the Secretary has provided notice to the retailer of all previous violations at that outlet;
> (E) establishing that civil money penalties for multiple violations shall increase from one violation to the next violation pursuant to paragraph (2) within the time periods provided for in such paragraph. . . .

Orton's theory is that CTP cannot meet these requirements unless it restricts itself to "charging one violation per transaction or inspection." Orton Br. at 16. Orton contends that CTP cannot provide "timely and effective notice" of "two violations in a single inspection." *Id*. at 17. Further, in order to provide "notice to the retailer of all previous violations" before charging another violation, Orton argues that an "inspection may

[13] Orton contends that Congress "intentionally drafted the provisions applicable to retailers to limit CTP to charging only one violation per inspection" because a "policy purpose" of the statute was to protect retailers from "overzealous enforcement." Orton Br. at 17, 19, 22. Yet at the same time, Orton characterized the penalties imposed on retailers as "the most severe" because repeated violations by retailers may lead to a no-tobacco-sale order which might "effectively end[] their business," whereas no analogous penalty is provided for manufacturers. Orton Br. at 18. While we agree that Congress provided various specific procedural protections to ensure retailers received due process and, as noted, provided a much-reduced scale capping CMPs, we do not see that Congress balanced the "severity of the penalty that retailers face" by any distinction as to how many violations may be recognized during an inspection as between retailers and manufacturers.

[14] We discuss in the next section Orton's claim that the procedural and notice provisions for retailer appeals imply that only one violation per inspection may be considered in setting a CMP amount.

inform a retailer that more than one instance of noncompliance was observed," but that inspection "can only result in the retailer being 'charged' with one 'violation' for purposes of assessing" a CMP. *Id*. at 16. Finally, Orton suggests that increasing CMP amounts "from one violation to the next violation" must mean the violations must occur during separate inspections. *Id*. at 17.

The construction which Orton seeks to put on these provisions is certainly not compelled by their language. FDA has issued guidance as instructed in both its regulations and, in more detail, in the explanations in its FDA Guidance documents. While, as we have said, FDA might have elected other approaches to interpreting and implementing the applicable law, we do not find that its guidance conflicts with the cited notice provisions. The requirement to provide "timely and effective notice" of each alleged violation does not set a limit on how many violations may be alleged after a particular inspection (or compliance check). Instead, 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 as CTP did here.

Similarly, providing notice to a retailer of all "previous violations" found at an outlet prior to charging that retailer for a violation does not necessarily imply that violations that occur at the same time (the same transaction or inspection) cannot be charged when observed. The events of the current inspection from which the charges arise are not "previous violations" but current violations.

Moreover, Congress could have specified in the TCA that the CMP amount increase with each failed inspection within a time frame instead of with the number of violations found within a time frame. Had it done so, there might be some basis for the interpretation which Orton propounds. The language Congress chose, however, is consistent with a concern that the more violations (acts constituting misbranding under the regulations Congress mandated) that one retailer committed, the more egregious its failure or inability to comply with the tobacco retailing regulations would appear, and hence the larger the CMP needed to remedy the fault and motivate compliance.

The regulations and FDA Guidance, issued under TCA section 103(q)(1), provide for due process hearings and notice of prior violations before any CMP is imposed. 21 C.F.R. Part 17; FDA Guidance at 8-9. FDA Guidance also provides for notice of the results of an inspection to a noncompliant retailer prior to another compliance check. FDA Guidance at 13-15. CTP has made it clear that a retailer such as Orton, whose prior violations affect the amount of the CMP imposed, would be entitled to notice of those violations and an opportunity to challenge in the hearing process before a CMP could be imposed, unless, as here, the retailer concedes the facts of the prior violations. CTP Br. at 9 n.12. The CMPs imposed for multiple violations do indeed increase based on the number of violations that occur within the set time periods. 21 C.F.R. § 17.2. In short,

CTP's interpretation reasonably implements everything called for under the TCA and nothing cited by Orton precludes recognizing multiple violations that are observed during a single transaction or inspection.

f. CTP's interpretation is not undercut by its treatment of multiple violations during a first inspection.

Orton argues that the FDA Guidance is not entitled to any deference on the ground that it is "internally inconsistent" in treating multiple instances of noncompliance during the first inspection as a single violation and multiple instances of noncompliance in subsequent inspections as individual violations. Orton Br. at 27; *see also* ALJ Decision at 2 (CTP "acknowledges" it will "treat multiple 'violations' as a single 'violation' on the first inspection, whereas the same 'violations' are counted 'individually' on subsequent inspections.") Orton ties its contention that the distinction "does not make sense" to its argument, which we have rejected above, that the statute demands that retailers be afforded notice and an opportunity to correct after each individual violation before any enforcement action (including calculation of a CMP amount based on those violations) may properly occur. We see no such guarantee in the statute.

The relevant language of the FDA Guidance nowhere suggests an inconsistent interpretation of the meaning of a "violation" for purposes of enforcing the Act. On the contrary, the FDA guidance clearly refers to multiple "violations" being found during the first failed inspection. FDA Guidance at 14. The FDA Guidance merely expresses a **discretionary policy choice** to count "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." *Id*. Such leniency in the case of a retailer being cited for the first time is within the discretion of an enforcement agency and is on its face a reasonable choice to educate and encourage retailers to come into compliance. If such remediation does not occur, CTP "may count any or all violations and its general policy is to count all of them individually." *Id*. Such a policy choice is no different than the decision in the FDA Guidance to use the lower CMP schedule until standards for training programs are issued, which the ALJ called a "reasonable exercise of discretion." ALJ Decision at 6.

We conclude that the FDA Guidance consistently defines violations as acts that fail to comply with any regulatory requirements and result in misbranding of tobacco products, regardless of how many tobacco products are affected or how many transactions or inspections are involved. CTP thus reasonably asserts it has authority to increase the CMP amounts based on the total number of such violations and the time frame over which they occur, while also exercising the discretion to waive consideration of more than one violation from the first failed inspection.

### 3. The ALJ improperly applied criminal law concepts, such as "rule of lenity" and "multiplication of charges" to remedial administrative actions under the Act.

It is well-established that remedial civil legislation is to be construed broadly to effectuate its public policy purposes. This principle has been expressly applied to the Act by the Supreme Court. *United States v. Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. at 798 ("[R]emedial legislation such as the [Act] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."); *see also* CTP Br. at 14-15 n.18, and cases cited therein. Orton has not shown any basis to think that the principles underlying this broad construction changed in any way as a result of the amendment of the Act by the TCA.

Despite acknowledging that the present proceeding is administrative (and civil) in nature, not criminal, the ALJ nevertheless imported the "rule of lenity" from criminal law, thus imposing a narrow construction on the provisions of the Act. ALJ Decision at 3. He did so after characterizing remedial CMPs as "punitive." *Id.* at 4, 6. This was error. An administrative enforcement approach, such as the graduated CMP scheme here, is intended to serve such remedial purposes as motivating compliance, reducing the risks of sales to minors, and protecting the public health, rather than focusing on punishment for wrongdoing. The Board has explained, in the context of a mandatory exclusion imposed by the Inspector General from federally-funded health care programs under section 1128 of the Social Security Act, that "rule of lenity applies only to criminal statutes" not to civil administrative enforcement. *Douglas Schram, R.Ph.*, DAB No. 1372, at 13 (1992). Furthermore, the Board has held that both the exclusion and CMP authorities under section 1128 are "civil and remedial rather than criminal and punitive," pointing to its goals in protecting "the funds of Federal health care programs and the programs' beneficiaries and recipients from untrustworthy providers." *Joann Fletcher Cash*, DAB No. 1725, at 10 (2000). While the Board has recognized that some civil penalties may be so severe as to raise double jeopardy questions, such a conclusion would require the "clearest proof" to "override legislative intent and transform what has been denominated a civil remedy into a criminal penalty." DAB No. 1725, at 11, quoting *Hudson v. United States*, 522 U.S. 93, 94 (1992).

Moreover, the Board has rejected such claims in relation to other provisions of the Act itself, finding the FDA's imposition of CMPs to be remedial not punitive. *TMJ Implants, Inc.,* DAB No. 2163, at 64 (2008). We can find no support for viewing the CMP in this case as punitive and note that Orton did not even choose to challenge the reasonableness of the amount of the CMP much less claim it is punitive. Respondent's Legal Memorandum in Response to the November 5, 2015 [ALJ] Order Requesting Brief at 23 n.7.

Contrary to the ALJ, we conclude that the Act is properly construed broadly to carry out its purposes, including those embodied in the TCA which we set out earlier in this decision. Such broad construction further supports our conclusion that CTP's interpretation is permissible.

The ALJ's analysis is simply misplaced in the administrative context. As mentioned before, the ALJ framed his analysis of how many violations occurred for purposes of applying the CMP amount schedule in terms of identifying "units of prosecution" based on his concern about an unwarranted multiplication of charges. ALJ Decision at 3. In so doing, he relied largely on one decision in a criminal case. *Id*. at 3-5; *United States v. Rentz*, 777 F.3d 1105. This analysis was error given that the proceeding does not involve criminal charges at all, but rather, as we have noted, administrative remedies.

Orton argues that the idea of a "unit of prosecution" is also employed in some administrative adjudication, and that the ALJ could use criminal principles against "piling on" penalties as "helpful interpretive tools" even though they admittedly did not constitute "binding precedent." Orton Br. at 10-14, and n.7. Even if we accepted the utility of such tools here, which we do not, the cases cited by Orton (and the ALJ) do not support the ALJ's conclusions.

For example, Orton points to a D.C. Circuit opinion to show that courts may use the unit of prosecution concept in administrative contexts. *Id*. at 11, citing *Nat'l Ass'n of Home Builders v. Occupational Safety and Health Admin.*, 602 F.3d. 464 (D.C. Cir. 2010). In that case, the court considered whether the Secretary of Labor had authority to define a violation of standards requiring respirators (as counted per-employee affected) by regulation rather than through adjudication. The court concluded that, in civil as in criminal contexts, "setting units of prosecution rests on policy judgments" and hence appropriately lies with the legislatures and regulators rather than adjudicators that apply the resulting standards. *Id*. at 468. Furthermore, the court held that the Secretary's interpretation of the governing statute as conferring authority to determine the unit of prosecution in OSHA enforcement cases was entitled to deference. *Id*. Thus, as we do here, the court deferred to the appropriate discretion of the regulator to interpret and make policy in defining the measure of a violation.

The concern about multiplying charges in the criminal law context arises largely from the Double Jeopardy Clause of the Constitution, which precludes punishing an accused twice for the same crime. *United States v. Long*, 2016 WL 2654053, at *2 (D.S.D. May 6, 2016) (emphasis added). Even in that context, no improper multiplication of charges may be found if the two counts charged under the same statute each require "proof of an element not required by the other." *Id.,* citing *United States v. Carpenter*, 422 F.3d 738, 747 (8th Cir. 2005*)* and *Blockburger v. United States*, 284 U.S. 299, 304 (1932) ("[T]he test to be applied to determine whether there are two offenses or only one, is whether each provision requires proof of a fact which the other does not."). Double jeopardy does

not generally attach in civil administrative proceedings unless the sanction is so punitive in effect or purpose as to make a civil remedy into a criminal sanction. *Hudson v. United States*, 522 U.S. 99 (1997). CMP proceedings under the Act, as discussed earlier in this decision, are remedial and not punitive in nature.

As we have explained, the Act defines the scope of the statutory provision at section 331(k) as applicable to any act that results in misbranding a tobacco product by reference to violations of the regulatory requirements. 21 U.S.C. §§ 333(f)(9), 387c(a)(7)(B); 17 C.F.R. Part 1140. As mentioned earlier, the requirements of the regulation thus incorporated into the statute are independent of each other, in precisely the sense that each requirement requires proof of an element or factual component that the others do not. For example, a violation of section 1140.14(a) requires proof that a purchaser was under age 18 (regardless of whether the retailer verified their identification), whereas a violation of section 1140.14 may be shown if the purchaser was older than 18 but younger than 27 but only if identification was not verified. Thus, even were double jeopardy an issue in this administrative proceeding (which it is not), holding Orton responsible for each violation of a distinct regulatory requirement would not constitute improper multiplying of charges regardless of the fact that the regulatory requirements are charged under a single statutory provision.

The *Rentz* case on which the ALJ relies does not support a different outcome. The ALJ quotes *Rentz* as saying that in "seeking a statute's unit of prosecution . . . the feature that naturally draws our immediate attention is the statute's verb." ALJ Decision at 3, quoting 777 F.3d at 1109. In *Rentz*, one shot from one gun resulted in a bullet hitting two people during a drug crime. The issue involved a sentence enhancement for anyone "who, during and in relation to any crime of violence or drug trafficking crime . . . uses or carries a firearm." 18 U.S.C. § 924(c)(1)(A). The aspect that the court was trying to sort out was that defendant used a gun once but the bullet hit two people. 777 F.3d at 1107. The verb to which the court paid immediate attention was "uses." Parsing the statutory language, the court concluded that one cannot be found to have used a gun under the prohibited circumstances more times than the number of times one has used a gun at all. *Id*. at 1108-11. But, besides the obvious factual and legal distinctions between that criminal case and this administrative civil enforcement case, the present case does not resemble *Rentz* because Orton did not simply commit a single act that happened to cause multiple consequences. The retailer (or its clerks) may have made one relevant sale on each relevant date but, in the course of conducting each transaction, each clerk did two separate and independent actions: sold tobacco to a minor purchaser and failed to verify identification.

In sum, administrative civil enforcement actions and criminal prosecutions remain distinct processes, serving different purposes and governed by different principles. Thus, we conclude that the criminal law analogies propounded by Orton in support of the ALJ's reasoning do not alter our analysis.

4. **CTP is authorized to impose a CMP in the amount of $500**.

Having found that CTP's method of determining the number of violations for purposes of applying the CMP penalty scale rests on a reasonable and permissible interpretation of the statute and regulations, we apply it here. Under that method, since Orton has admitted the facts of three countable violations within a 24-month period, CTP is authorized under both the statute and the regulations to impose a CMP of $500.

Furthermore, even under the ALJ's erroneous legal analysis, his conclusion as to applicable remedies was improper and exceeded his authority. The ALJ found, based on the stipulated facts, that Orton "misbranded a package of . . . cigarettes on May 16, 2015, by (a) selling the cigarettes to a person under the age of 18 and (b) failing to demand photographic identification from the purchaser," and that the same was true on July 10, 2013. ALJ Decision at 6. He noted that 22 months elapsed "between the two cases of misbranding." *Id*. He then decided that it was "unnecessary" to determine the "legal efficacy of the 'Warning Letter"" that CTP sent Orton after the May 2015 inspection, because "the quantity and frequency of the established incidents of misbranding authorize but one penalty." *Id*., citing 21 C.F.R. § 17.2. He then opined that, notwithstanding having found, even under his interpretation of the Act, two "incidents of misbranding" within 22 months (which calls for a $250 CMP), the "only permissible sanction" is a $0 CMP and a Warning Letter, the latter of which he proceeded to issue himself. *Id*. at 7.

The ALJ's reasoning appears to rely on the idea that CTP's issuance of a Warning Letter somehow may have failed to provide Orton "sufficient notice to defend itself" and should have been preceded by due process of some sort under the Administrative Procedure Act (5 U.S.C. § 551 et seq.). *Id*. at 6. Despite first stating that he did not need to discuss either theory, the ALJ later said that he was reverting to the lowest penalty level "[b]ecause this is the first instance in which the Respondent has received the process required by statute." *Id*. at 7.[15] Orton expands on the ALJ's comments in its brief to us. Orton Br. at 29. Orton argues that it was "entitled to a hearing before receiving a civil penalty of $0.00 and a warning letter." *Id*., citing TCA 103(q)(1); 21 U.S.C. 333 note. Hence, according to Orton, it was "not afforded an opportunity to contest the facts of its first alleged violation before receiving that penalty." *Id*.

This argument misreads the statute. Section 103(q)(1)(C), as we quoted earlier, provides for a hearing under the FDA regulations for assessing CMPs. When no CMP is imposed (which is what a $0 CMP effectively means), nothing in the statute or CMP regulations

[15] While ALJs may evaluate the reasonableness of a particular CMP amount *(see, e.g., Quick Stop, L.L.C./Rashid Sherwani d/b/a Quick Stop*, DAB CR1337 (2015) ($5,000 fine reduced to $2,500)), the ALJ in this case did not purport to be doing so here. Instead, he erroneously held, on putative due process grounds, that no penalty could be imposed.

provides for a hearing prior to issuance of a Warning Letter.[16] A legitimate concern might arise if CTP sought to impose a CMP after a later inspection found further violations but treated those violations addressed in the Warning Letter as not subject to challenge during a valid appeal of a CMP based on the multiple violations including those at the initial and later inspections. CTP, however, expressly states that, had Orton not stipulated to the facts as to the initial inspection, CTP "was prepared to prove [them] in this action. . . ." CTP Br. at 5, n.7. Thus, no CMP is being imposed here prior to a hearing on the basis for the CMP.

The ALJ's effort to undertake to issue his own "Warning Letter" lacks authority and improperly conflates the role of adjudicator with that of an enforcement agency. The regulations permit the ALJ to review a CMP which CTP seeks to impose (21 C.F.R. 17.1), and in appropriate cases may alter the amount of a CMP (21 C.F.R. 17.34, 17.45), but the authority of the ALJ to conduct hearings on CMPs does not extend to issuing his own Warning Letter (21 C.F.R. 17.19). While a CTP Warning Letter is not in itself a sanction and does not constitute final agency action, its content advises the recipient of sanctions which may be imposed if it does not subsequently comply with applicable requirements. CTP Br. at 28, and cases cited therein. Issuing warning of potential sanctions is an enforcement function of the agency, whereas determining whether imposition of a sanction is authorized based on a due process hearing is an adjudicative function. While the ALJ has considerable discretion to set procedures to carry out his responsibilities under 21 C.F.R. Part 17, that discretion does not extend to assigning himself new responsibilities nowhere allocated to him. The ALJ's purported Warning Letter is void and of no effect.

[16] CTP points out that warning letters are employed in many other areas of FDA authority, apart from tobacco sales, to motivate voluntary compliance by regulated entities before the FDA pursues an enforcement action, whether an administrative CMP or civil remedies or criminal penalties before a court. CTP Reply Br. at 8-9; CTP Br. at 5, nn. 7, 8. Were FDA required to conduct hearings prior to each of the 17,232 warning letters it reports issuing in 2015, the administrative costs and burden may be assumed to be great. *Id*.

**Conclusion**

For the reasons explained above, we reverse the ALJ Decision and impose a CMP of $500 based on Orton's three violations of tobacco sale requirements in a 24-month period.

/s/
Sheila Ann Hegy

/s/
Christopher S. Randolph

/s/
Leslie A. Sussan
Presiding Board Member