

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

Western Spirits, Inc. d/b/a T-Joe's Steakhouse and Saloon  
Docket No. A-17-96  
Decision No. 2844  
January 16, 2018

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

Appellant Western Spirits, Inc., d/b/a T-Joe's Steakhouse and Saloon (Western Spirits or Respondent) timely appeals the Initial Decision issued by an Administrative Law Judge (ALJ) on June 15, 2017, imposing a civil money penalty (CMP) in the amount of \$11,000 against Western Spirits for committing seven violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations within a 48-month period. *Western Spirits, Inc., d/b/a T-Joe's Steakhouse and Saloon*, DAB TB1480 (2017) (ALJ Decision). The ALJ issued her decision following a hearing on an administrative complaint (Complaint) filed by the Center for Tobacco Products (CTP) of the Food and Drug Administration (FDA) in which CTP alleged the following violations, each occurring on three separate occasions within the 48-month period: 1) impermissibly selling tobacco products to minors; 2) failing to verify, by means of photo identification containing a date of birth, that a purchaser of cigarettes was 18 years of age or older; and 3) utilizing a tobacco products vending machine in a non-exempt facility. For the reasons explained below, we find the ALJ Decision free of legal error and supported by substantial evidence. We therefore affirm the decision and sustain the CMP of \$11,000.

**Applicable Law**

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” and authorizes the issuance of CMPs against any person who intentionally violates that prohibition. 21 U.S.C. §§ 331(k), 333(f)(9). A tobacco product is misbranded if sold or distributed in any state in violation of regulations issued under the Act. 21 U.S.C. § 387c(a)(7)(B). The FDA may impose CMPs against “any person who violates a requirement of [the Act] which relates to tobacco products . . . .” 21 U.S.C. § 333(f)(9). The Act directed the Secretary 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 implementing regulations at 21 C.F.R. Part 1140 prohibit the sale of cigarettes or smokeless tobacco “to any person younger than 18 years of age” (i.e., a minor); require retailers to “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 prohibit the sale of cigarettes or smokeless tobacco using a vending machine in a non-exempt facility. 21 C.F.R. § 1140.14(a), (b), (c).<sup>1</sup> Failure to comply with the applicable provisions 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).

Regulations governing FDA CMPs specify the maximum CMP amounts FDA may impose for violations based on the number of violations and the period of time in which they are committed. For the time period relevant here,<sup>2</sup> \$11,000 was the maximum CMP amount that CTP could impose for six or more violations within a 48-month period. 21 C.F.R. § 17.2.

The CMP hearing regulations permit a retailer to appeal a CMP 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). CTP initiates a case before the ALJ by serving a Complaint on the retailer (21 C.F.R. § 17.5) and filing it with the Civil Remedies Division (CRD) of the Departmental Appeals Board. The retailer (the respondent in the administrative appeal proceedings) requests a hearing by filing an answer to the Complaint within 30 days but may request one 30-day extension. 21 C.F.R. § 17.9(a), (c). If the respondent does not file an answer within the prescribed time, the ALJ “shall assume the facts alleged in the complaint to be true” and enter a default judgment “if such facts establish liability under the relevant statute . . . .” 21 C.F.R. § 17.11(a). Assuming a timely answer, the case proceeds to hearing before the ALJ according to the procedures set forth in 21 C.F.R. Part 17.

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

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<sup>1</sup> We cite to the regulations in effect when CTP conducted the inspection of Respondent’s facility that led to this appeal and as of the date CTP served its Complaint on Respondent.

<sup>2</sup> The \$11,000 CMP assessed here was the maximum allowed under section 17.2 on both the date of the December 22, 2015 inspection and the date FDA filed the Complaint, which was July 8, 2016.

## Case Background<sup>3</sup>

### 1. The Complaint and the Hearing

On July 8, 2016, CTP served a Complaint on Western Spirits at its place of business, 12700 East Interstate 80 Service Road, Cheyenne, Wyoming 82009. The Complaint sought a penalty of \$11,000 for seven alleged violations of the Act and its implementing regulations within 48 months. ALJ Decision at 2; CRD Docket (Dkt.) Entry 1 and 1b. The Complaint alleged that on December 22, 2015, an FDA-commissioned inspector inspected Western Spirits and found the following violations of the Act and regulations: 1) impermissibly selling tobacco products to minors; 2) failing to verify the purchaser was 18 years of age or older by means of photo identification containing a date of birth; and 3) utilizing a tobacco products vending machine in a non-exempt facility. ALJ Decision at 1, 2; CRD Dkt. Entry 1, at 3-4. The Complaint specifically alleged that during the December 22, 2015 inspection, “a person younger than 18 years of age was able to enter the establishment and purchase a tobacco product from the vending machine. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.” CRD Dkt. Entry 1, at 3-4. On July 11, 2016, CTP filed a copy of the Complaint with the Departmental Appeals Board Civil Remedies Division to initiate the administrative adjudication proceedings leading to this appeal. ALJ Decision at 2; CRD Dkt. Entry 1. In addition to charging Western Spirits with the alleged violations found on the December 22, 2015 inspection, the Complaint noted that the CRD had entered a final default judgment against Western Spirits on a prior Complaint charging Western Spirits with violations of the same three regulatory provisions, as found during inspections on April 25, 2015 and December 12, 2014. CRD Dkt. Entry 1, at 4; *see also* ALJ Decision at 6-7.

Respondent timely filed an Answer and Response to Complaint that denied the allegations. CRD Dkt. Entries 3, 4.<sup>4</sup> On December 29, 2016, CTP filed its pre-hearing exchange, which included 17 exhibits, including two witness declarations. ALJ Decision at 2; CRD Dkt. Entries 15 and 15a-r. Respondent did not file a pre-hearing exchange and did not propose to present any witnesses in its case. ALJ Decision at 2. The ALJ held a hearing by telephone on March 15, 2017 for the purpose of admitting the exhibits and giving Respondent an opportunity to cross-examine CTP’s witnesses. *Id.* At the hearing, the ALJ admitted all of CTP’s exhibits. Transcript (Tr.) at 10. Respondent, appearing pro se, cross-examined the following CTP witnesses: Steven Melia, the FDA inspector

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<sup>3</sup> The factual findings stated here are taken from the ALJ Decision and the administrative record. We make no new findings of fact, and the facts stated are undisputed unless we indicate otherwise.

<sup>4</sup> The document in CRD Dkt. Entry 4 appears to be a duplicate of the document in CRD Dkt. Entry 3.

who conducted the December 22, 2015, inspection at Western Spirits (Tr. at 18-34) and Laurie Sternberg, a CTP Senior Regulatory Counsel (Tr. at 54-57). *See also* CTP Exhibits (Exs.) 4, 8 (direct testimony of CTP’s witnesses). Following the hearing, which was transcribed, each party filed a post-hearing brief. *See* CRD Dkt. Entries 20-23.

## 2. The ALJ Decision

The ALJ found that “[t]he testimonies of Mr. Melia and Ms. Sternberg plus the corroborating evidence consisting of photographs of the pack of cigarettes that were obtained from the minor on December 22, 2015, and the photographs of the vending machine, are proof that Respondent unlawfully sold tobacco products to a minor, failed to check the minor’s identification before making the sales, and used a vending machine in a non-exempt facility.” ALJ Decision at 4. The ALJ rejected Respondent’s argument that the sale could not have occurred because, Respondent claimed, “no sale from the vending machine can occur without first speaking with the bartender . . . in order for a switch to be turned on to allow the vending machine to make the sale.” *Id.*, citing Respondent’s Brief (Br.) at 5-6. The ALJ also rejected Respondent’s argument “that he has video surveillance of the vending machine at all times.” *Id.* The ALJ rejected those arguments because “no . . . evidence [of the alleged video surveillance] was presented . . .” and “Respondent’s argument without supporting evidence that the sale could not have occurred because of a lock on the vending machine is not sufficient to establish that the sale to a minor did not occur . . . .” *Id.* Citing the inspector’s testimony “that the minor entered the establishment without cigarettes,” the ALJ concluded that “the only reasonable explanation that I can find for her emerging from the establishment with cigarettes is that she purchased them in the establishment.” *Id.*

The ALJ also found “without merit” Respondent’s arguments that the FDA regulations have no authority in Wyoming and that he had a right to a jury trial under the Seventh Amendment to the United States Constitution. *Id.* Under the Supremacy Clause, the ALJ concluded, federal law controls in conflicts between federal and state law. *Id.* The ALJ also concluded that Congress clearly intended the FDA to have authority to pursue penalties for violations of the Tobacco Control Act (Pub. L. 111-31, H.R. 1256)<sup>5</sup> since Congress “specifically gave the FDA the authority to impose civil money penalties for a violation of the prohibition against the sale of tobacco products to any person under the age of 18.” ALJ Decision at 4-5, citing 21 U.S.C. § 331(f)(9); 21 C.F.R. § 1140.14(a)(1). Respondent was not entitled to a jury trial, the ALJ found, because “the right to a jury trial is not present under the Tobacco Control Act,” and the Supreme Court has held that “[t]he 7th Amendment is not a bar to an administrative hearing.” *Id.* at 5 (case citations omitted).

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<sup>5</sup> The ALJ’s reference, more fully stated, is to the Family Smoking Prevention and Tobacco Control Act, Pub. L. 111-31, H.R. 1256 (June 22, 2009).

The ALJ thus concluded that CTP had established Respondent’s liability for a CMP under 21 U.S.C. § 333(f)(9) and proceeded to determine the amount of the CMP under the factors set forth in the Act. *Id.* The ALJ found \$11,000 an appropriate amount. *Id.* at 5-7. The ALJ noted that Respondent did not present any arguments with regard to the factors she was required to consider but relied solely on its argument that it had not committed any violations, an argument the ALJ had already rejected. *Id.* at 5, 6.

## Discussion

### A. *Western Spirits has not shown that it is an “exempt facility.”*

The regulations governing Board review specify that a Notice of Appeal (NA) “must identify specific exceptions to the initial decision, must support each exception with citations to the record, and must explain the basis for each exception.” 21 C.F.R. § 17.47(c). Respondent’s Notice of Appeal identifies an exception to the ALJ’s determination that it violated 21 C.F.R. § 1140.14(c) by “the use of a vending machine in a non-exempt facility.”<sup>6</sup> NA at 2. Section 1140.14(c) states:

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)[.]

*See also Kathy & Johnny, Inc., d/b/a Conoco at Brighton Blvd./Shell*, DAB No. 2775, at 9 (2017) (holding that section 1140.14(c) “unambiguously establishes that the presence of a . . . vending machine in a retail facility accessible to minors constitutes a violation”). The referenced section 1140.16(c)(2)(ii), as relevant here, excepts from this prohibition “[v]ending machines . . . that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.”

Respondent claims *Western Spirits* qualifies as an “exempt facility” under section 1140.16(c)(2)(ii) because “[u]nder Wyoming law, no one under the age of 21 is legally permitted to enter a bar [and] [i]n accordance with state statutes, the testimony below established that [*Western Spirits*] had signs posted in and outside of the bar giving notice that individuals under the age of 21 are not permitted to enter.” NA at 2. We find no merit to Respondent’s argument that it qualifies as an “exempt facility.”

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<sup>6</sup> Respondent does not dispute that it sold tobacco products to a person under 18 years of age and that it did not verify, by identification bearing the person’s date of birth, that the person was 18 years of age or older, the other two violations alleged.

Respondent's reliance on Wyoming law is misplaced since this case, as the ALJ concluded, is governed by federal law (the Act and its implementing regulations) not state law.<sup>7</sup> Moreover, the case involves laws addressing access to tobacco products by minors, not access to alcohol.

Respondent's statement about Wyoming law also is inaccurate. As CTP points out, *see* CTP Br. at 9, Wyoming law does not prohibit persons under 21 from entering a bar. Rather, Wyoming law prohibits persons under 21 from purchasing and consuming alcoholic beverages and from "[e]nter[ing] or remain[ing] in an establishment that is primarily for off-premise sales of alcoholic liquor or malt beverages unless accompanied by a parent, spouse or legal guardian who is twenty-one (21) year of age or older." W.S. 1977 § 12-6-101(c) (emphasis added). Western Spirits is a bar (and restaurant), not "an establishment that is primarily for off-premise sales of alcoholic liquor or malt beverages . . . ." Even if Western Spirits was not a bar but, instead, an establishment that primarily made off-premise sales of alcohol or malt beverages, under the Wyoming statute on which Respondent relies, minors would be allowed to enter Western Spirits if "accompanied by a parent, spouse or legal guardian who is twenty-one (21) year of age or older."<sup>8</sup> *Id.*

The factual premise for Respondent's assertion, that testimony in the ALJ hearing "established that [Western Spirits] had signs posted in and outside of the bar giving notice that individuals under the age of 21 are not permitted to enter," is also flawed. NA at 2. Respondent makes no citation to the record to support its assertion of what the record "established";<sup>9</sup> nor does Respondent's statement accurately reflect the record. The only testimony about signage was a response the CTP inspector gave during cross-examination. The inspector stated only that there was "a sign," not "signs" (plural), and his testimony did not specify whether the sign was inside or outside the bar.<sup>10</sup> Tr. at 21. The inspector also did not testify that the sign he agreed was present stated that no person under the age of 18 could buy cigarettes; indeed, since the inspector testified that the sign

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<sup>7</sup> We note that although Respondent continues to cite Wyoming law, Respondent does not specifically dispute, or even discuss, the ALJ's conclusion that federal law controls.

<sup>8</sup> Since Wyoming law does not govern FDA inspections or prohibit entry of minors into a bar, there also is no basis for Respondent's assertion that the FDA inspector violated Wyoming law by "sending a minor into the bar to solicit a sale of cigarettes . . . ." NA at 2. We also note, as did CTP, *see* CTP Br. at 9 n.2, that Wyoming law grants immunity from prosecution under W.S. 1977 § 12-6-103 to minors conducting a compliance check regarding prohibited alcohol sales. W.S. 1977 12-6-103(d)(v). Wyoming law also prohibits the sale of tobacco products to persons under 18 but grants immunity from prosecution for minors who make such purchases during compliance inspections. *Compare* W.S. 1977 §§ 14-3-304(a) and 14-3-305(a) *with* W.S. 1977 14-3-307(d)(vi).

<sup>9</sup> Respondent's failure to cite the record is a failure to comply with the requirement of section 21 C.F.R. § 17.47(c) that a Notice of Appeal "must support each exception with citations to the record . . . ."

<sup>10</sup> CTP's other witness was not on site during the inspection.

referred to needing to be 21, his testimony strongly suggests the sign addressed access to alcohol under Wyoming law, not access to tobacco products. Nor did Respondent itself present evidence of any signs addressing prohibition of access to tobacco products for minors (or access to alcohol for that matter).

Respondent also makes bald assertions concerning the location of the vending machine in an attempt to show that the machine could not be accessed by minors. It states that “uncontradicted” evidence of record establishes that the vending machine was “well within the confines of the bar” which was “completely separate from the restaurant” and that the vending machine was “in a separate part of the building not open to minors.” Appellant’s Reply Brief (Reply Br.) at 2, 3. Respondent has not produced any evidence proving what Respondent asserts. We also note that the photographs the inspectors took of the vending machine show no visible warning sign stating that minors may not purchase cigarettes. *See* CTP Exs. 12 and 13.

*B. Respondent’s argument that it did not violate the regulations because it took “all reasonable measures to prevent the entry of a minor” is not material.*

Respondent does not dispute on appeal the ALJ’s finding that the evidence of record established the sale of the cigarettes to the minor during the inspection. Instead, Respondent argues that the sale of cigarettes did not violate the Act or regulations because Respondent “has taken all reasonable measures to prevent the entry of a minor in protected or exempt facility.” NA at 2; *see also* Reply Br. at 1-4. We have already concluded, in the prior section, that Respondent has not shown that it is an exempt facility and, thus, need not address here that part of its statement. We address here why we reject Respondent’s “reasonable measures” argument.

The “reasonable measures” Respondent says it took include alleged “notices posted that minors were not legally allowed into the facility.” NA at 2. (We assume this is a reference to the alleged “signs” we discussed in the prior section of our decision.) Respondent also alleges it had an “on/off switch to the cigarette machine . . . located behind the bar in the facility and only accessible to bar personnel who knew of its existence.” *Id.* Respondent did not make the signage argument before the ALJ, and the ALJ rejected the “on/off switch” argument because Respondent presented no supporting evidence. *See* ALJ Decision at 4. Respondent does not dispute on appeal the ALJ’s findings regarding the lack of evidence to support its assertions regarding the alleged “on/off switch”, and we find no basis to disturb those findings.<sup>11</sup> More importantly,

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<sup>11</sup> Respondent also argued before the ALJ that it had video surveillance of the cigarette machine, but the ALJ noted that the record contained no evidence to support that claim either. ALJ Decision at 4. Respondent does not mention a video surveillance system in its appeal briefs.

however, we reject Respondent’s “all reasonable measures” argument because, as we explain below, even if Respondent had presented evidence supporting these measures, which it did not, taking “all reasonable measures” would not avoid a violation of the regulations.

Respondent’s assertion that it posted notices that minors were not legally allowed into the facility is immaterial, in the first place, because that assertion addresses state law for access to liquor by persons under 21, not access to cigarettes for persons under 18. But even assuming the assertion addressed federal law for access of minors to cigarettes, it would be immaterial because the exception in section 1140.16(c)(2)(ii) applies only to “[v]ending machines . . . that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.” (Emphasis added.) Even assuming Western Spirits, at the time of the December 2015 inspection, had posted the notices it claims and had implemented other “reasonable measures,” like the alleged “on/off switch,” the minor who accompanied the inspector to Western Spirits for the inspection actually entered the bar and purchased the cigarettes from the vending machine. Thus, Respondent did not “ensure that no person younger than 18 years of age is present, or permitted to enter, at any time” as required by section 1140.16(c)(2). Putting it another way, the vending machine was unlawfully accessible to minors within the meaning of the Board’s holding in *Kathy & Johnny*, DAB No. 2775, *supra*, since a minor, in fact, was able to access it.

*C. The “record discrepancy” Respondent alleges does not exist and would not be relevant in any event.*

The last exception to the ALJ Decision identified by Respondent is an alleged “record discrepancy” that Respondent alleges “makes the Complainant’s [penalty] calculation unsupported.” Reply Br. at 4-5. The “discrepancy” Respondent alleges involves the testimony of Mr. Melia, the inspector who conducted the December 22, 2015 inspection of Western Spirits, that he did two inspections at Western Spirits, one involving a male minor and the other a female minor. *See* Tr. at 24, 26. Respondent claims that the ALJ’s basing the amount of the CMP on seven violations of the Act is inconsistent with this testimony. NA at 3; Reply Br. at 4-5. There is no merit to this argument. The fact that Mr. Melia may have done an inspection at Western Spirits in addition to the December 22, 2015 inspection at issue here is not relevant to calculation of the CMP. The undisputed record establishes that in addition to the December 22, 2015 inspection which Mr. Melia conducted, there were two other inspections at Western Spirits, on December 12, 2014 and April 25, 2015, respectively. *See* CTP Exs. 1, 2 and 3. How many or which of those additional inspections Mr. Melia conducted is irrelevant. Moreover, as CTP notes (CTP Br. at 14), Respondent appears to be confusing the number of inspections at Western Spirits with the number of individual violations found during those inspections. The ALJ based her determination of the amount of the CMP on the fact that Respondent

committed three violations of the Act on each of three separate occasions within a 48-month period and on her consideration of the factors specified at 21 U.S.C. § 333(f)(5)(B). ALJ Decision at 5-7. The violations found on the two inspections prior to the December 22, 2015, inspection, as the ALJ noted, became final “by way of a default judgment entered on October 29, 2015.” ALJ Decision at 7; *see also Western Spirits, Inc., d/b/a T-Joe’s Steakhouse and Saloon*, FDA Docket Number FDA-2015-H3131, CRD Docket Number C-15-3920.<sup>12</sup> *Id.* Thus, the three CTP inspections found a total of nine violations.

CTP, however, followed its usual discretionary enforcement policy and counted only one violation (rather than three) from the first inspection. *See* ALJ Decision at 7 n.2; *see also* Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions at 13 (Revised Dec. 2016);<sup>13</sup> *Orton Motor Co., d/b/a Orton’s Bagley*, DAB No. 2717, at 12-15 (2016). As noted earlier, \$11,000 is the maximum CMP that can be imposed based on six or more violations within a 48-month period. 21 C.F.R. § 17.2. Thus, the CMP imposed here is within the legally permitted maximum CMP amount.

The ALJ noted that in determining the amount of the CMP, she was required to consider “the nature, circumstances, extent[,] and gravity of the [violation or] violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.” ALJ Decision at 5-6, citing 21 U.S.C. § 333(f)(5)(B). Addressing those factors, the ALJ found that “[t]he repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the [CMP] amount should be set accordingly.” *Id.* at 6. The ALJ also found the amount of the CMP proposed by CTP consistent with the fact that “[t]he current action is the second [CMP] action brought against Respondent since September 2, 2015 for violations of the Act and its implementing regulations” and involved the same violations. *Id.* at 6-7. In addition, the ALJ found Respondent “fully culpable for all seven violations . . . .” *id.* at 7, and noted that Respondent had not provided any evidence with respect to its ability (or inability) to pay an \$11,000 CMP or asserted any mitigating factors, *id.* at 6. The ALJ concluded, “I agree with CTP that [t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” *Id.* at 7, citing Complainant’s Informal Br. at 11.

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<sup>12</sup> The default judgment can be found in the record of the present case as CTP Exhibit 3.

<sup>13</sup> The FDA Guidance can be found at <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf>.

On appeal, Respondent identifies no dispute regarding the ALJ's considerations of the factors and raises no argument at all challenging the amount of the CMP except for the "discrepancy" argument we rejected above. Accordingly, we uphold the ALJ's determination that an \$11,000 CMP was lawful and appropriate.

### **Conclusion**

We conclude that the ALJ Decision is legally sound and its factual basis is supported by substantial evidence. We affirm the ALJ Decision and sustain the \$11,000 penalty that the ALJ found appropriate and entered against Respondent.

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/s/  
Constance B. Tobias

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/s/  
Susan S. Yim

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/s/  
Sheila Ann Hegy  
Presiding Board Member