

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

32 Ave Valero Corp  
d/b/a Valero,

Respondent.

Docket No. T-19-1719  
FDA No. FDA-2019-H-0855

Decision No. TB4149

Date: July 31, 2019

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, 32 Ave Valero Corp d/b/a Valero, at 1121 Southwest 32nd Avenue, Miami, Florida 33135, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Valero impermissibly sold covered tobacco products to a minor and failed to verify, by means of photo identification containing a date of birth, that the covered tobacco product purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint also alleges that Respondent previously sold covered tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The complaint further alleges that Respondent Valero previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks an \$11,410 civil money penalty against Respondent Valero for seven violations within a 48-month period.

During the hearing process, Respondent failed to comply with multiple judicial orders and directions. I, therefore, strike Respondent's answer and issue this decision of default judgment.

## **I. Background**

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on February 26, 2019, CTP served the complaint on Respondent Valero by United Parcel Service. On March 19, 2019, Respondent timely filed its answer. On March 26, 2019, I issued an Acknowledgment and Pre-hearing Order (APHO) setting forth case procedures and deadlines. The APHO contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until May 3, 2019, to request that the other party provide copies of documents relevant to this case. APHO ¶ 12. The APHO also stated that, pursuant to 21 C.F.R. § 17.23(a), a party receiving such a request must provide the requested documents no later than 30 days after the request has been made. *Id.* The parties were warned that failure to comply with any order including the APHO may result in sanctions. *Id.* ¶ 16.

On May 15, 2019, CTP filed a Motion to Compel Discovery stating that its request for production of documents (RFP) was sent to Respondent on April 5, 2019, and delivered to Respondent's retail establishment on April 8, 2019. CTP further stated that it did not receive a response from Respondent regarding its RFP, and requested that I issue an order requiring Respondent to comply. A May 21, 2019 letter issued by my direction allowed Respondent until June 5, 2019, to file a response to CTP's Motion to Compel Discovery. Respondent failed to file a response to CTP's Motion to Compel Discovery or otherwise to respond to the May 21, 2019 letter. Therefore, on June 6, 2019, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by June 21, 2019. I warned Respondent that failure to comply with my order may result in sanctions, including the issuance of an initial decision and default judgment finding Respondent liable for the violations alleged in the complaint and imposing a civil money penalty.

On June 28, 2019, CTP filed a Status Report and Motion to Impose Sanctions stating that Respondent has not produced any documents as ordered. CTP requested I strike Respondent's answer and issue an initial decision and default judgment imposing a civil money penalty against Respondent. A July 2, 2019 letter issued by my direction allowed Respondent until July 15, 2019 to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has not responded to the Motion to Impose Sanctions or the July 2, 2019 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with multiple judicial orders and directions. Specifically, Respondent failed to comply with my March 26, 2019 APHO and my June 6, 2019 order requiring it to comply with CTP's RFP. Additionally, Respondent failed to file a response to CTP's Motion to Compel Discovery, CTP's Motion to Impose Sanctions, and the May 21, 2019 and July 2, 2019 letters. This

repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

## II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- On June 26, 2018, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-2687, FDA Docket Number FDA-2018-H-2441 (*see also* CRD Docket Number T-18-1646, FDA Docket Number FDA-2018-H-1130), against Respondent for five<sup>1</sup> violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 1121 Southwest 32nd Avenue, Miami, Florida 33135, on July 7, 2017, February 4, 2018, and May 10, 2018;
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- At approximately 9:11 AM on November 24, 2018, at Respondent's business establishment, 1121 Southwest 32nd Avenue, Miami, Florida 33135, an FDA-commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets Classic Grape cigars to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent Valero's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see also* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see also* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed. Reg. 28,974,

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<sup>1</sup> Two violations were documented on July 7, 2017, two on February 4, 2018, and two on May 10, 2018. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(b)(1), no retailer may sell covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, an \$11,410 civil money penalty is permissible for seven violations of the regulations found at 21 C.F.R. pt. 1140 within a 48-month period.

### **Order**

For these reasons, I enter default judgment in the amount of \$11,410 against Respondent 32 Ave Valero Corp d/b/a Valero. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

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/s/  
Wallace Hubbard  
Administrative Law Judge