

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-2793)

Complainant

v.

Madison Tobacco, Inc.
d/b/a Tobacco Shop,

Respondent.

Docket No. T-18-2980

Decision No. TB3536

Date: February 19, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Madison Tobacco, Inc. d/b/a Tobacco Shop, at 29087 Dequindre Road, Madison Heights, Michigan 48071, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Tobacco Shop impermissibly sold covered tobacco products to a minor and failed to verify, by means of photo identification containing a date of birth, that the 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, failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and used a self-service display in a non-exempt facility. The complaint further alleges that Respondent Tobacco Shop previously admitted to four violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose an \$11,182 civil money penalty against Respondent Tobacco Shop.

I. Background and Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 24, 2018, CTP served the complaint on Respondent Tobacco Shop by United Parcel Service. On August 22, 2018, Respondent timely filed an answer. On August 24, 2018, I issued an Acknowledgment and Pre-Hearing Order (APHO) acknowledging receipt of Respondent's answer and establishing procedural deadlines for this case. 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 October 1, 2018, to request that the other party provide copies of documents relevant to this case. APHO ¶ 12. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a). *Id.*

On August 31, 2018, CTP served its Request for Production of Documents on Respondent. On October 31, 2018, CTP filed a Motion to Compel Further Responses to Complainant's Request for Production of Documents (Motion to Compel Discovery) stating it has not received a complete response to its Request for Production of Documents and requesting "an order be entered compelling Respondent to produce all documents responsive to CTP's Request for Production of Documents forthwith."

In a November 9, 2018 letter issued by my direction, Respondent was given until November 16, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent failed to file any response to CTP's Motion to Compel Discovery or otherwise respond to the November 9, 2018 letter. Therefore, in a December 4, 2018 order, I granted CTP's motion and ordered Respondent to comply with CTP's Request for Production of Documents by December 20, 2018. I also extended the parties' pre-hearing exchange deadlines by 30 days. I warned Respondent that a failure to comply might result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the complaint and imposing a civil money penalty.

On January 3, 2019, CTP filed a Motion to Impose Sanctions stating, "Respondent has not produced documents to CTP in response to its RFP." CTP requested I strike Respondent's answer and issue a default judgment imposing a civil money penalty in the amount of \$11,182 against Respondent. In a January 16, 2019 amended letter issued by my direction, Respondent was given until January 22, 2019, to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has failed to file any response to CTP's Motion to Impose Sanctions.

The issue before me is whether CTP's proposed sanction – striking Respondent's Answer and issuing default judgment – is the appropriate one. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. *See* 21 C.F.R. § 17.35(b). Respondent failed to comply with my

August 24, 2018 APHO and Respondent failed to comply with my December 4, 2018 order to comply with CTP's Request for Production of Documents. This conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default. Therefore, pursuant to 21 C.F.R. § 17.35, I grant CTP's Motion to Impose Sanctions, and strike Respondent's answer for failing to comply with two judicial directions.

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 December 4, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-555, FDA Docket Number FDA-2017-H-6713, against Respondent for four¹ violations of 21 C.F.R. pt. 1140 within a thirty-six month period. CTP alleged those violations to have occurred at Respondent's business establishment, 29087 Dequindre Road, Madison Heights, Michigan 48071, on January 25, 2017, November 17, 2017, and November 20, 2017;
- 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 1:13 PM on May 26, 2018, at Respondent's business establishment, 29087 Dequindre Road, Madison Heights, Michigan 48071, an FDA commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets Tropical Fusion 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 Tobacco Shop'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* 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

¹ Two violations were documented on January 25, 2017, one on November 17, 2017, and two on November 20, 2017. 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.

regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed. Reg. 28,974, 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. § 1140.16(c), no retailer may use a self-service display in a non-exempt facility.

Under 21 C.F.R. § 17.2, an \$11,182 civil money penalty is permissible for six violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$11,182 against Respondent Madison Tobacco, Inc. d/b/a Tobacco Shop. 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.

/s/
Wallace Hubbard
Administrative Law Judge