

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

Center for Tobacco Products,  
(FDA No. FDA-2018-H-2113)

Complainant

v.

The Deters Company  
d/b/a Blue Pantry,

Respondent.

Docket No. T-18-2408

Decision No. TB3426

Date: January 11, 2019

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, The Deters Company d/b/a Blue Pantry, at 7230 Turfway Road, Florence, Kentucky 41042, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Blue Pantry 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 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 Blue Pantry previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,591 civil money penalty against Respondent Blue Pantry.

During the hearing process, Respondent failed to comply with two judicial directions regarding CTP's discovery request. 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 June 6, 2018, CTP served the complaint on Respondent Blue Pantry by United Parcel Service. Respondent timely filed an answer, in which, Respondent admitted the allegations in the complaint but requested a reduced penalty amount.

On September 4, 2018, I issued an Acknowledgment and Pre-hearing Order (APHO) acknowledging receipt of Respondent's answer and 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 October 12, 2018, to request that the other party provide copies of documents relevant to this case. 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. The parties were warned that failure to comply with any order including the APHO may result in sanctions.

On November 9, 2018, CTP filed a Motion to Compel Discovery stating that it served its request for production of documents (RFP) on Respondent on September 24, 2018. 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. Respondent did not file a response to CTP's Motion to Compel Discovery. Therefore, on November 29, 2018, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by December 14, 2018. 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 listed in the complaint and imposing a civil money penalty.

On December 19, 2018, 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. In a December 20, 2018 letter issued by my direction, Respondent was given until January 3, 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 to the December 20, 2018 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 two separate judicial directions. Specifically, Respondent failed to comply with my September 4, 2018 APHO and Respondent failed to comply with my November 29, 2018 order requiring it to comply with CTP's RFP. Additionally, Respondent failed to respond to CTP's Motion to Impose Sanctions or the December 20, 2018 letter. 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 July 28, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-5488, FDA Docket Number FDA-2017-H-4448, against Respondent for three<sup>1</sup> violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's business establishment, 7230 Turfway Road, Florence, Kentucky 41042, on February 7, 2017, and May 21, 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 7:38 p.m. on April 24, 2018, at Respondent's business establishment, 7230 Turfway Road, Florence, Kentucky 41042, an FDA-commissioned inspector documented Respondent's staff selling a package of two Swisher Sweets 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 Blue Pantry'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 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.

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<sup>1</sup> Two violations were documented on February 7, 2017, and two on May 21, 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.

