

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

Center for Tobacco Products,

Complainant,

v.

Title 26 LLC
d/b/a Up In Smoke,

Respondent.

Docket No. T-19-998
FDA No. FDA-2018-H-4913

Decision No. TB3961

Date: June 11, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Title 26 LLC d/b/a Up In Smoke, at 3450B Bragg Boulevard, Fayetteville, North Carolina 28303, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Up In Smoke 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 Up In Smoke previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks an \$11,182 civil money penalty against Respondent Up In Smoke for seven violations within a 48-month period.

During the hearing process, Respondent failed to comply with multiple judicial orders. 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 January 4, 2019, CTP served the complaint on Respondent Up In Smoke by United Parcel Service. On February 4, 2019, after Respondent's answer was filed, 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 March 18, 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 March 26, 2019, CTP filed a Motion to Compel Discovery stating that its request for production of documents (RFP) was served on Respondent on February 14, 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. In my March 26, 2019 order, I allowed Respondent until April 10, 2019, to file a response to CTP's Motion to Compel Discovery. I warned Respondent that if it fails to respond, I may grant 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 March 26, 2019 order. Therefore, on April 12, 2019, I granted CTP's Motion to Compel Discovery and ordered Respondent to comply with CTP's RFP by April 26, 2019. I warned Respondent that failure to comply with my order may result in sanctions, including striking its filings and issuing an initial decision and default judgment finding Respondent liable for the violations alleged in the complaint and imposing a civil money penalty.

On May 1, 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. In my May 7, 2019 order, I allowed Respondent until May 16, 2019 to file a response to CTP's Motion to Impose Sanctions. I warned Respondent that if it fails to respond, I may grant CTP's Motion to Impose Sanctions. To date, Respondent has not responded to the Motion to Impose Sanctions or the May 7, 2019 order.

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. Specifically, Respondent failed to comply with my February 4, 2019 APHO and my April 12, 2019 order requiring it to respond to 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 March 26, 2019 and May 7, 2019 orders. 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 February 2, 2018, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-1139, FDA Docket Number FDA-2018-H-0496 (*see also* CRD Docket Number T-17-5576, FDA Docket Number FDA-2017-H-4544), against Respondent for five¹ 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, 3450-B Bragg Boulevard, Fayetteville, North Carolina 28303, on November 19, 2016, February 5, 2017, and January 13, 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 4:19 PM on October 7, 2018, at Respondent's business establishment, 3450-B Bragg Boulevard, Fayetteville, North Carolina 28303, an FDA-commissioned inspector documented Respondent's staff selling a package of two White Owl 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 Up In Smoke'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.

¹ Two violations were documented on November 19, 2016, two on February 5, 2017, and two on January 13, 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.

