## **Department of Health and Human Services**

### DEPARTMENTAL APPEALS BOARD

### **Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Sublime Plus Inc. d/b/a City Mini Mart,

Respondent.

Docket No. T-19-11 FDA Docket No. FDA-2018-H-3707

Decision No. TB3710

Date: April 11, 2019

### INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Sublime Plus Inc. d/b/a City Mini Mart, at 150 Belmont Avenue, Springfield, Massachusetts 01108, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. CTP seeks to impose an \$11,182 civil money penalty against Respondent for a total of six violations within a 48-month period. The complaint alleges that a previous civil money penalty action concluded after Respondent admitted to three violations of 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 subsequently sold regulated 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, thereby further violating the Act and its implementing regulations.

During the course of these administrative proceedings, Respondent failed to comply with orders and procedures governing this proceeding and failed to defend its actions, which interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's Answer and issue this decision of default judgment.

### I. Procedural History

On October 3, 2018, CTP served the complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. On November 2, 2018, Respondent, through counsel, timely answered CTP's complaint. On November 5, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges, including a schedule for discovery. I directed that a party receiving a discovery request must provide the requested documents within 30 days of the request. APHO ¶ 12; see 21 C.F.R. § 17.23(a). I warned:

I may impose sanctions including, but not limited to, dismissal of the complaint or answer, if a party fails to comply with any order (including this order), fails to prosecute or defend its case, or engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing. 21 C.F.R. § 17.35.

## APHO ¶ 16.

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on November 15, 2018. On January 4, 2019, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. By letter issued at my direction, Respondent was informed that it had until January 22, 2019, to file a response to CTP's Motion to Compel Discovery. *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent did not respond.

On January 25, 2019, I issued an Order to Compel Discovery in which I granted CTP's motion and ordered Respondent to produce responsive documents to CTP's Request for Production of Documents by February 8, 2019. I stated:

I warn Respondent that failure to comply may **result in sanctions**, which may include striking its filings and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty. 21 C.F.R. § 17.35.

January 25, 2019, Order to Compel Discovery (emphasis in original).

On February 15, 2019, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent had not complied with my Order to Compel Discovery, and asked that I strike Respondent's Answer as a sanction and issue an Initial Decision and Default Judgment. By Order of February 20, 2019, I informed Respondent that it had until March 4, 2019, to file a response to CTP's Motion to Impose Sanctions. I warned: "If Respondent fails to file a response, I may grant CTP's Motion to Impose Sanctions in its entirety." February 20, 2019, Order (emphasis in original). Respondent did not respond.

# II. Striking Respondent's Answer

I may sanction a party for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

21 C.F.R. § 17.35(a).

Respondent failed to comply with the following orders and procedures governing this proceeding:

- Respondent failed to comply with 21 C.F.R. § 17.23(a) and paragraph 12 of my APHO, when Respondent failed to respond to CTP's Request for Production of Documents within 30 days; and
- Respondent failed to comply with my January 25, 2019, Order to Compel Discovery, when it failed to submit the documents responsive to CTP's Request for Production of Documents by February 8, 2019.

Respondent failed to defend its action despite the following opportunities:

- By letter issued at my direction, Respondent was informed that it had until January 22, 2019, to file a response to CTP's Motion to Compel Discovery. Respondent did not defend its action; and
- By Order of February 20, 2019, I informed Respondent that it had until March 4, 2019, to file a response to CTP's Motion to Impose Sanctions. Respondent did not defend its action.

I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend its case, and, as a result, interfered with the speedy, orderly,

and fair conduct of this proceeding. I conclude that Respondent's conduct establishes a basis for sanctions pursuant to 21 C.F.R. § 17.35, and that sanctions are warranted.

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). Here, Respondent failed to comply with two of my orders, despite my explicit and repeated warnings that its failure could result in sanctions. I specified that those sanctions may include striking its Answer and "issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." January 25, 2019, Order to Compel Discovery. Respondent also failed to defend its actions, despite my express reminders of the opportunity. Respondent's repeated misconduct interfered with the speedy, orderly, or fair conduct of this proceeding. I find that Respondent's actions are sufficient to warrant striking its Answer and issuing a decision by default, without further proceedings. 21 C.F.R. § 17.35(b), (c)(3). Accordingly, I strike Respondent's Answer. 21 C.F.R. § 17.35(c)(3).

### II. Default Decision

Striking Respondent's Answer leaves the complaint unanswered. Therefore, I am required to issue an initial decision by default, provided that the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Pursuant to 21 C.F.R. § 17.11(a), I am required to "assume the facts alleged in the complaint to be true" and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its complaint:

- On July 18, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-16-1128, FDA Docket Number FDA-2016-H-1831, against Respondent for violations of 21 C.F.R. pt. 1140, three<sup>1</sup> of which occurred within the 48-month period relevant here. CTP alleged those violations to have occurred at Respondent's business establishment located at 150 Belmont Avenue, Springfield, Massachusetts 01108, on March 31, 2015, and December 30, 2015;
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary

<sup>1</sup> Two violations were documented on March 31, 2015, and two on December 30, 2015. In accordance with customary practice, CTP counted the violations identified during the initial inspection as a single violation, and, unless otherwise indicated, counted subsequent violations individually.

penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";

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- At approximately 11:33 AM on September 2, 2017, at Respondent's business establishment located at 150 Belmont Avenue, Springfield, Massachusetts 01108, an FDA-commissioned inspector documented Respondent's staff selling a package of two Garcia y Vega Game Mango 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;
- In a warning letter dated November 9, 2017, CTP informed Respondent of the inspector's September 2, 2017 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action<sup>2</sup>;
- At approximately 11:32 AM on July 5, 2018, at Respondent's business establishment located at 150 Belmont Avenue, Springfield, Massachusetts 01108, an FDA-commissioned inspector documented Respondent's staff selling a package of two Garcia y Vega Game Blue 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 City Mini Mart'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, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1) and (b)(1),³ no retailer may sell regulated tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i) and (b)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no regulated tobacco product purchasers are younger than 18 years of age.

<sup>&</sup>lt;sup>2</sup> In accordance with customary practice, it appears that CTP counted the violations identified in the September 2, 2017 inspection immediately preceding the warning letter, as a single violation and subsequent violations individually.

<sup>&</sup>lt;sup>3</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <a href="https://federalregister.gov/a/2016-10685">https://federalregister.gov/a/2016-10685</a>.

An \$11,182 civil money penalty is permissible under 21 C.F.R. § 17.2, for six 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 \$11,182 against Respondent Sublime Plus Inc. d/b/a City Mini Mart. 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/ Catherine Ravinski Administrative Law Judge