

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Minmax Corporation
d/b/a Amera,

Respondent.

Docket No. T-19-330
FDA Docket No. FDA-2018-H-4103

Decision No. TB4091

Date: July 17, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Minmax Corporation d/b/a Amera, at 2200 West Allegheny Avenue, Philadelphia, Pennsylvania 19132, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. CTP seeks an \$11,182 civil money penalty against Respondent for a total of seven 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, within a 48-month period. The complaint alleges that a previous civil money penalty action concluded after Respondent admitted to five violations of the regulations. The complaint further alleges that Respondent subsequently sold regulated 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 Act and its implementing regulations an additional two times.

Respondent timely answered CTP's complaint; however 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, assessing a civil money penalty of \$11,182 against Respondent for seven violations within a forty-eight month period.

I. Procedural History

On October 31, 2019, CTP served the complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent, through counsel, timely filed an Answer. On December 19, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for filings and exchanges, including a schedule for discovery. I directed that a party receiving a Request for Production of Documents must provide the requested documents within 30 days of the request. APHO ¶ 12; *see* 21 C.F.R. § 17.23(a).

On February 21, 2019, CTP filed a Motion to Compel Discovery asserting that Respondent did not provide documents responsive to its Request for Production of Documents as required by my APHO and regulations. By Order of February 26, 2019, I informed Respondent of its deadline to file a response to CTP's Motion to Compel Discovery, and warned that if Respondent failed to respond, "I may grant CTP's motion in its entirety." *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent did not respond.

On March 14, 2019, I issued an Order to Compel Discovery in which I granted CTP's motion and ordered Respondent to produce documents responsive to CTP's Request for Production of Documents by March 29, 2019. I warned Respondent that:

[F]ailure 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.

March 14, 2019, Order to Compel Discovery (emphasis in original).

On May 30, 2019, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent did not produce responsive documents in compliance with my Order to Compel Discovery. By Order of May 30, 2019, I informed Respondent of its deadline to file a response to CTP's Motion to Impose Sanctions. I warned Respondent that if it failed to file a response, I may "**grant CTP's Motion to Impose Sanctions in its entirety.**" May 30, 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 March 14, 2019 Order to Compel Discovery, when it failed to produce documents responsive to CTP's Request for Production of Documents by March 29, 2019.

Respondent also failed to defend its action despite my February 26, 2019 and May 30, 2019 orders informing Respondent of such opportunities and warning of consequences.

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, or 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 warnings that its failure could result in sanctions. I specified that those sanctions "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." March 14, 2019, Order to Compel Discovery. Respondent also failed to defend its actions, despite my orders expressly reminding Respondent 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.

III. Default Decision

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

CTP alleges the following facts in its complaint:

- On March 8, 2018, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-1544, FDA Docket Number FDA-2018-H-0992, against Respondent for violations of 21 C.F.R. pt. 1140, five¹ of which occurred within the 48-month period relevant in the current complaint. CTP alleged those violations to have occurred at Respondent's business establishment located at 2200 West Allegheny Avenue, Philadelphia, Pennsylvania 19132, on April 21, 2016, May 31, 2017, and February 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 12:14 PM on August 10, 2018, at Respondent's business establishment located at 2200 West Allegheny Avenue, Philadelphia, Pennsylvania 19132, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes 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 Amera's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded

¹ Two violations were identified on April 21, 2016, two on May 31, 2017, and two on February 10, 2018. *See also* CRD Docket Number T-17-5271; FDA Docket Number FDA-2017-H-4208. In accordance with FDA policy, CTP counted the violations identified during the initial inspection as a single violation and all violations identified during subsequent inspections individually.

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),² 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), 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.

An \$11,182 civil money penalty is permissible under 21 C.F.R. § 17.2, 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 \$11,182 against Respondent Minmax Corporation d/b/a Amera. 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/
Margaret G. Brakebusch
Administrative Law Judge

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.