

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

JP Front Minimarket, Inc.
d/b/a JP Front Mini Market,

Respondent.

Docket No. T-19-237
FDA Docket No. FDA-2018-H-3996

Decision No. TB3829

Date: May 14, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, JP Front Minimarket, Inc. d/b/a JP Front Mini Market, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$11,182. CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff sold regulated tobacco products to minors and failed to verify that purchasers were of sufficient age, 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. CTP seeks a civil money penalty of \$11,182, for six violations of the regulations within a 48-month period.

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 24, 2018, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent timely filed its Answer to CTP's Complaint. On November 28, 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 that I may impose sanctions if a party failed to comply with any order, including the APHO. APHO ¶ 16.

On January 24, 2019, CTP filed a Motion to Compel Discovery asserting that Respondent did not respond to its discovery request as required by my APHO and regulations. By Order of January 25, 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 February 21, 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 discovery request by March 13, 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.

February 21, 2019, Order to Compel Discovery (emphasis in original).

On March 22, 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 March 26, 2019, I informed Respondent of its deadline to file a response to CTP's motion and warned Respondent that if it failed to file a response, "**I may grant CTP's Motion to Impose Sanctions in its entirety.**" March 26, 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 February 21, 2019 Order to Compel Discovery, when it failed to submit the documents responsive to CTP's Request for Production of Documents by March 13, 2019.

Respondent also failed to defend its action despite my January 25, 2019, and March 26, 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 a regulation governing this proceeding. 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." February 21, 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, and issue this Initial Decision and Default Judgment, assuming the facts alleged in CTP's Complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

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 [C]omplaint 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:

- Respondent owns JP Front Mini Market, an establishment that sells tobacco products and is located at 4803 North Front Street, Philadelphia, Pennsylvania 19120. Complaint ¶¶ 7-8.
- CTP initiated a civil money penalty action on August 1, 2016, CRD Docket Number T-16-1315, FDA Docket Number FDA-2016-H-2056, against Respondent for violations of 21 C.F.R. pt. 1140, three¹ of which occurred during the 48-month period relevant in the current Complaint. Complaint ¶ 13.
- The previous action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge, "finding that all of the violations alleged in the Complaint occurred." Complaint ¶¶ 13-14.
- On December 9, 2017, an FDA-commissioned inspector conducted a subsequent inspection of Respondent's establishment during which "a person younger than 18 years of age was able to purchase a package of two Garcia y Vega Game Green cigars . . . at approximately 3:46 PM." Additionally, "the minor's identification was not verified before the sale" Complaint ¶ 11.
- On December 28, 2017, CTP issued a Warning Letter to Respondent regarding the inspector's documented violations from December 9, 2017. The letter explained that the documented violations constituted violations of federal regulations, and that the named violations were not necessarily an exhaustive list of all violations at the establishment. The Warning Letter also stated that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that it is Respondent's responsibility to comply with the law. Complaint ¶¶ 11-12.
- On October 3, 2018, an FDA-commissioned inspector conducted a subsequent inspection of Respondent's establishment during which "a person younger than

¹ One violation was identified on April 27, 2015, and two on January 13, 2016.

18 years of age was able to purchase a package of two Garcia y Vega Game Pineapple cigars . . . at approximately 6:10 PM.” Additionally, “the minor’s identification was not verified before the sale” Complaint ¶ 9.

These facts establish that Respondent is liable 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. § 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). The regulations prohibit the sale of regulated tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1), (b)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser’s date of birth, that no regulated tobacco product purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i), (b)(2)(i).

Taking the above alleged facts as true, Respondent had at least six violations of regulations found at 21 C.F.R. pt. 1140 within a 48-month period. Respondent violated the prohibition against selling regulated tobacco products to persons younger than 18 years of age on April 27, 2015, January 13, 2016, December 9, 2017, and October 3, 2018. 21 C.F.R. § 1140.14(a)(1), (b)(1). On January 13, 2016, December 9, 2017, and October 3, 2018, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no regulated tobacco product purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i), (b)(2)(i). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$11,182, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$11,182 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge