

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Tezee, Inc.
d/b/a Rite-Nau,

Respondent.

Docket No. T-19-177
FDA Docket No. FDA-2018-H-3927

Decision No. TB4153

Date: July 30, 2019

**ORDER CLARIFYING DISMISSAL AND
ENTERING INITIAL DECISION AND DEFAULT JUDGMENT**

On June 17, 2019, I entered an order dismissing the hearing request filed by Respondent, Tezee, Inc. d/b/a Rite-Nau, based on Respondent's failure to file a pre-hearing exchange and its subsequent failure to respond to an order to show cause that I issued on May 30, 2019. The Center for Tobacco Products (CTP) now moves that I reopen this case, contending that I inadvertently sanctioned CTP by dismissing the administrative complaint.

This order clarifies my intent. I dismiss Respondent's hearing request for failure to comply with my pre-hearing orders and order to show cause, and for abandonment. Additionally, I enter the following default judgment.

DECISION

The CTP filed an Administrative Complaint (Complaint) against Respondent, Tezee, Inc. d/b/a Rite-Nau, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$559. 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 impermissibly sold cigarettes and covered 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 \$559 for at least three violations within a 24-month period.

During the course of these administrative proceedings, Respondent failed to comply with orders and procedures governing this proceeding and failed to defend this action, 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 hearing request and issue this decision of default judgment.

I. Procedural History

On October 19, 2018, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent timely answered CTP's Complaint on November 13, 2018.¹ 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:

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 December 21, 2018. On February 8, 2019, CTP

¹ On November 27, 2018, by email transmission, CTP forwarded Respondent's Answer dated November 12, 2018 to the Civil Remedies Division. I note that the envelope in the record is postmarked November 13, 2018.

filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. On February 14, 2019, a letter issued by my direction advised Respondent that it had until March 1, 2019, to file a response to CTP's Motion to Compel Discovery. *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent failed to submit a response to CTP's Motion to Compel or the February 14, 2019 letter, or otherwise comply with CTP's Request for Production of Documents.

On March 5, 2019, I issued an Order granting CTP's Motion to Compel Discovery and ordered Respondent to produce responsive documents to CTP's Request for Production of Documents by March 19, 2019. I warned:

Failure to [comply] 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.

March 5, 2019 Order, at 1-2. In the same Order, I also extended the parties' pre-hearing exchange deadlines. *Id.* at 2.

On April 22, 2019, CTP filed its pre-hearing exchange. To date, Respondent has not filed its pre-hearing exchange, which was due not later than May 10, 2019. On May 30, 2019, I issued an Order to Show Cause (OSC) giving Respondent until June 14, 2019 to show cause why its hearing request should not be dismissed and a default judgment in favor of CTP entered on the grounds of abandonment. Respondent did not file a response to my OSC. On June 17, 2019, in accordance with the regulations at 21 C.F.R. § 17.35², I issued an order dismissing the case for abandonment.

² The regulations provide, in part:

(a) The presiding officer may sanction a person, including any party or counsel for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action;

* * * * *

(b) Any such sanction, including, but not limited to, those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

* * * * *

(e) If a party fails to prosecute or defend an action under this part after service of a notice of hearing, the presiding officer may dismiss the action or may issue an initial decision imposing penalties and assessments.

On July 9, 2019, CTP filed a Motion to Reopen and Motion to Impose Sanctions (Motion). In its Motion, CTP argues:

Respondent did not respond to the ALJ's Order to Show Cause. Rather than enter default judgment in favor of CTP as the ALJ stated in its May 30, 2019 order . . . the ALJ *dismissed* the case on the grounds of Respondent's abandonment . . . Rather than sanction *Respondent* by dismissing the answer it filed and entering an initial decision and default judgment in CTP's favor as the ALJ stated that he would in its May 30, 2019 order, the ALJ's June 17, 2019 order sanctions *CTP* by dismissing the case. (Original emphasis.)

FDA's regulations governing this proceeding provide that a presiding officer may sanction a party for failing to defend an action or failing to comply with an order, including a failure to defend its case. *See* 21 C.F.R. § 17.35(a) . . . FDA's regulations specify that a presiding officer may strike the pleadings of the party failing to comply with a discovery order. 21 C.F.R. § 17.35(c)(3) . . . Paragraph 16 of the APHO also states that a party's failure to comply with any order in this proceeding, or failure to defend its case, may result in sanctions including dismissal of the answer.

Given Respondent's failure to file its pre-hearing exchange and its failure to respond to the ALJ's Order to Show Cause, sanctions against Respondent are an appropriate remedy here. Respondent was on notice that such sanctions could result given the regulations, 21 C.F.R. § 17.35, as well as the ALJ's May 30, 2019 order.

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).

21 C.F.R. § 17.35(a), (b), (e).

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 May 30, 2019 Order when it failed to show cause why the case should not be dismissed for abandonment and a default judgment entered by June 14, 2019.

Respondent failed to defend its action despite the following opportunity:

- By letter issued by my direction on February 14, 2019, Respondent was informed that it had until March 1, 2019, to file a response to CTP's Motion to Compel Discovery. Respondent failed to respond to CTP's Motion to Compel or otherwise respond to the February 14, 2019 letter.

I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend this action, 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 three of my orders, despite my explicit warnings that its failure could result in sanctions. I specified that those sanctions may include striking its Answer and "issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." APHO ¶ 16; May 5, 2019, Order at 1-2. Respondent also failed to defend this action, despite express reminders of the opportunity through letters issued by my direction. 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 Rite-Nau, an establishment that sells tobacco products and is located at 3780 Oberlin Avenue, Lorain, Ohio 44053. Complaint ¶¶ 7-8.
- An FDA-commissioned inspector conducted an inspection of Respondent’s establishment on December 17, 2017, at approximately 1:54 PM, during which “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” Additionally, “the minor’s identification was not verified before the sale” Complaint ¶ 11.
- On January 4, 2018, CTP issued a Warning Letter to Respondent regarding the December 17, 2017 inspection. The letter explained that the inspector documented violations of federal law, and that the named violations were not necessarily intended to be 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.
- An FDA-commissioned inspector conducted a subsequent inspection of Respondent’s establishment on July 29, 2018, at approximately 3:17 PM, during which “a person younger than 18 years of age was able to purchase a Black & Mild cigar . . . [.]” 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) and 21 C.F.R. § 1140.14(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 purchasers are

younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i) and 21 C.F.R. § 1140.14(b)(2)(i).

Taking the above-alleged facts as true, Respondent violated the prohibition against selling regulated tobacco products to persons younger than 18 years of age on December 17, 2017, and July 29, 2018. 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(b)(1). On those same dates, 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 purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i) and 21 C.F.R. § 1140.14(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 \$559, which is a permissible penalty for three violations of the regulations found at 21 C.F.R. pt. 1140 within a 24-month period. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$559 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge