

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-2609)

Complainant

v.

Three “T”s in Pensacola, Inc.
d/b/a Red Baron Lounge and Package,

Respondent.

Docket No. T-17-3819

Decision No. TB2587

Date: April 3, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Three “T”s in Pensacola, Inc. d/b/a Red Baron Lounge and Package, located at 8961 Pensacola Boulevard, Pensacola, Florida 32534, and by filing a copy of the complaint with the Food and Drug Administration’s (FDA) Division of Dockets Management. The complaint alleges that Red Baron Lounge and Package impermissibly sold cigarettes to minors, failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and used a vending machine in a non-exempt facility, 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 to impose a \$2,236 civil money penalty against Respondent Red Baron Lounge and Package.

During the course of this administrative proceeding, Respondent has failed to comply with two separate judicial orders and failed to appear at the pre-hearing conference. *See*

21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. §§ 17.35(a)(1), (2), I strike Respondent's Answer and issue this decision of default judgment.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$2,236 civil money penalty, on Respondent Three "T"s in Pensacola, Inc. d/b/a Red Baron Lounge and Package on May 9, 2017. Respondent filed an Answer to CTP's complaint on May 24, 2017. I issued an Acknowledgment and Prehearing Order (APHO) on July 3, 2017, that set deadlines for parties' submissions, including the August 2, 2017 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. CTP served Respondent with its request for documents on August 2, 2017. On September 19, 2017, CTP filed an Unopposed Motion to Extend Deadlines due to Hurricane Irma. On September 20, 2017, I issued an Order Granting CTP's Motion to Extend Deadlines that extended the deadline for the parties to serve requests for documents to October 2, 2017.

On October 10, 2017, CTP filed a Motion to Compel Discovery, indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). On the same date, CTP also filed a Motion to Extend Deadlines requesting that all pre-hearing exchange deadlines be extended for 30 days. In a letter issued by my direction, Respondent was given until October 27, 2017, to object to CTP's Motion to Compel Discovery. Respondent did not file an objection to CTP's motion.

In an October 30, 2017 Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until November 15, 2017 to comply with CTP's discovery request. CTP subsequently filed a Status Report, indicating that Respondent had provided the requested documents. On December 22, 2017, CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange.

On January 18, 2018, I issued an Order Scheduling Pre-Hearing Conference, setting a pre-hearing conference by telephone for January 30, 2018, at 11:00 a.m. Eastern Time. On January 30, 2018, I convened the previously scheduled Pre-Hearing Conference by telephone. CTP's counsel joined the pre-hearing conference, but Respondent failed to appear.

On January 30, 2018, I issued an Order to Show Cause, allowing Respondent until February 9, 2018 to provide an explanation for failure to appear at the pre-hearing conference. My Order to Show Cause warned Respondent that "[f]ailure to do so 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 pursuant to 21 C.F.R. § 17.35(a).” To date, Respondent has not responded to my Order to Show Cause.

II. Striking Respondent’s Answer

Pursuant to 21 C.F.R. § 17.35(a), 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.

Here, Respondent failed to:

- Comply with my January 18, 2018, Order Scheduling Pre-Hearing Conference when it failed to appear at the January 30, 2018, pre-hearing conference; and
- Comply with my January 30, 2018, Order to Show Cause when it failed to show cause for its failure to appear at the pre-hearing conference.

I find that Respondent failed to comply with two judicial orders and failed to defend its actions, which has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). 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 orders, despite being warned that failure to comply could result in sanctions including issuance of an Initial Decision and Default Judgment; Respondent also failed to appear for a previously scheduled pre-hearing conference. I find that Respondent’s failure to comply is 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).

III. Default Decision

Striking Respondent’s Answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a

penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R. § 17.11. Specifically:

- At approximately 6:51 p.m. on April 2, 2016, at Respondent's business establishment, 8961 Pensacola Boulevard, Pensacola, Florida 32534, an FDA-commissioned inspector documented a person younger than 18 years of age purchase a package of Marlboro Gold Pack 100's cigarettes from a vending machine. 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. Additionally, the inspector documented the use of a vending machine in a non-exempt facility;
- In a warning letter dated April 14, 2016, CTP informed Respondent of the inspector's April 2, 2016 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;
- At approximately 5:07 p.m. on December 28, 2016, at Respondent's business establishment, 8961 Pensacola Boulevard, Pensacola, Florida 32534, an FDA-commissioned inspector documented a person younger than 18 years of age purchase a package of Marlboro cigarettes from a vending machine. 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. Additionally, the inspector documented the use of a vending machine in a non-exempt facility.

These facts establish Respondent Red Baron Lounge and Package'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* 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). Under 21 C.F.R. § 1140.14(a)(1)¹, no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(3), no retailer may use a vending machine to sell cigarettes in a non-exempt facility.

Order

For these reasons, I enter default judgment in the amount of \$2,236 against Respondent Three "T"s in Pensacola, Inc. d/b/a Red Baron Lounge and Package. 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