

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

J.A.C. Fine Wine and Spirits, Inc.
d/b/a Friendly Liquors,

Respondent.

Docket No. T-17-5813
FDA No. FDA-2017-H-4844

Decision No. TB2447

Date: February 12, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, J.A.C. Fine Wine and Spirits, Inc. d/b/a Friendly Liquors, at 1567 Acushnet Avenue, New Bedford, Massachusetts 02746, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Friendly Liquors impermissibly sold cigarettes or smokeless tobacco 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 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. The complaint likewise alleges that an Initial Decision and Default Judgment was entered against Respondent Friendly Liquors for three previous violations. Therefore, CTP seeks to impose a \$5,591 civil money penalty against Respondent Friendly Liquors.

During the course of the administrative proceedings, Respondent failed to comply with two judicial orders and failed to defend its case, 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

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 14, 2017, CTP served the Complaint on Respondent Friendly Liquors by United Parcel Service. Respondent timely answered CTP's Complaint on September 8, 2017. On September 14, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges and warned that I may impose sanctions if a party failed to comply with any order, including the APHO. APHO at ¶¶ 4, 16. In the APHO I set a deadline of October 23, 2017, for party discovery requests; December 5, 2017, for CTP's pre-hearing exchange; and December 26, 2017, for Respondent's pre-hearing exchange. *Id.* at ¶ 4. On December 5, 2017, CTP timely filed its pre-hearing exchange.

On October 24, 2017, Respondent filed a letter and five pages of unmarked documents, presumably in response to CTP's discovery request. However, Respondent did not file a pre-hearing exchange by the December 26, 2017 deadline, or at any time thereafter.

On January 3, 2018, I issued an Order Scheduling Pre-Hearing Conference. In this order, I set a pre-hearing conference by telephone for January 23, 2018, at 1:00 PM Eastern Time, to resolve certain issues and schedule a hearing for this case. Respondent was reminded of the conference by telephone message on January 22, 2018, and by emails on January 22, 2018, and January 23, 2018. However, Respondent did not appear at the scheduled pre-hearing conference call, nor did Respondent respond to the order, telephone message, or email communications.

Accordingly, on January 24, 2018, I issued an Order to Show Cause, in which I provided Respondent until February 6, 2018, to show cause for its failure to appear at the pre-hearing conference. I warned Respondent that:

Failure 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.

(Emphasis in original.)

To date, Respondent has not responded to my Order to Show Cause. Indeed, Respondent has been silent since its October 24, 2017 filing.

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.

21 C.F.R. § 17.35(a).

Here, Respondent failed to:

- Comply with my January 3, 2018, Order Scheduling Pre-Hearing Conference when it failed to appear at the January 23, 2018, pre-hearing conference; and
- Comply with my January 24, 2018, Order to Show Cause when it failed to show cause for its failure to appear at the pre-hearing conference.

Respondent failed to comply with two judicial orders – despite multiple reminders and warning of sanctions if it failed to comply. I find that Respondent failed to comply with orders and procedures governing this proceeding 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 repeatedly failed to comply with my orders, despite my explicit warning that its failure could result in sanctions and I specified that those sanctions may include “issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty.” I find that Respondent's repeated 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, provided that the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must first 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 (but not its conclusory statements) and I conclude that default judgment is merited based on the allegations of the Complaint. 21 C.F.R. § 17.11. Specifically:

- On April 21, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-16-170, FDA Docket Number FDA-2016-H-0454, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 1567 Acushnet Avenue, New Bedford, Massachusetts 02746, on August 1, 2015, and November 22, 2015;
- 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";
- At approximately 5:37 PM on June 14, 2017, at Respondent's business establishment, 1567 Acushnet Avenue, New Bedford, Massachusetts 02746, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro 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 Friendly Liquors' 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); 81 Fed. Reg.

¹ An FDA-commissioned inspector documented two violations on August 1, 2015 (sale to a minor and failure to verify the age of a purchaser through photographic identification), and two violations on November 22, 2015 (sale to a minor and failure to verify the age of a purchaser through photographic identification). In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1),² no retailer may sell cigarettes or smokeless tobacco 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 cigarette or smokeless tobacco purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$5,591 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,591 against Respondent J.A.C. Fine Wine and Spirits, Inc. d/b/a Friendly Liquors. 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/
Wallace Hubbard
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>.