

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

FC and G, Inc.
d/b/a Summit Cigar,

Respondent.

Docket No. T-17-708
FDA No. FDA-2016-H-3796

Decision No. TB1671

Date: July 20, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, FC and G, Inc. d/b/a Summit Cigar, at 200 North State Street, Clarks Summit, Pennsylvania 18411, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Summit Cigar impermissibly sold tobacco products 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 utilized a self-service display 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. The Complaint likewise alleges that Respondent Summit Cigar previously admitted to four violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose an \$11,002 civil money penalty against Respondent Summit Cigar.

During the course of the administrative proceedings in this case, Respondent has failed to comply with four separate judicial orders, and to defend its case.

Furthermore, Respondent's misconduct has interfered with the speedy and orderly conduct of the hearing process. 21 C.F.R. § 17.35(a)(1)-(3). 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 November 21, 2016, CTP served the Complaint on Respondent Summit Cigar by United Parcel Service. Respondent timely answered CTP's Complaint. On January 13, 2017, 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 at ¶ 12; 21 C.F.R. § 17.23(a).

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on March 1, 2017. On April 7, 2017, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. By Order of April 11, 2017, Respondent was informed that it must file a response to CTP's Motion to Compel Discovery not later than April 24, 2017 pursuant to 21 C.F.R. § 17.32(c). Respondent did not respond.

Accordingly, on May 11, 2017, I issued an Order to Compel Discovery granting CTP's motion and ordering Respondent to comply with CTP's Request for Production of Documents by May 19, 2017. Respondent was warned that:

Failure to comply **will result in sanctions**, which 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. 21 C.F.R. § 17.35.

Emphasis in original.

On June 14, 2017, CTP filed an Updated Status Report and Motion to Extend Deadlines. CTP reported that Respondent had yet to comply with my May 11, 2017 Order to Compel Discovery directing compliance by May 19, 2017. However, based on June 2, 2017 correspondence from Respondent indicating that it intended to comply, CTP asked that I afford Respondent an additional opportunity to comply before CTP sought sanctions. By Order of June 16, 2017, I granted CTP's motion and extended the deadlines, allowing Respondent until June 23, 2017 to comply with my May 11, 2017 Order to Compel Discovery, and granting CTP until June 30, 2017 to file a motion for sanctions if Respondent once again failed to comply.

On June 30, 2017, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent had not complied with my Order to Compel Discovery. CTP requested that Respondent's answer be stricken and a default judgment be issued in its favor. On June 30, 2017, Respondent immediately responded to CTP's motion by email apologizing for not complying with the discovery request "as fast as planned," noting that it is "[s]till under construction," and is "not good with computers" I do not find Respondent's communication sufficient to excuse its numerous failures to comply with deadlines, the administrative process, and four separate judicial orders issued during the past six months, as detailed below.

II. Striking Respondent's Answer

Respondent failed to:

- Respond to CTP's March 1, 2017 Request for Production of Documents within 30 days in accordance with 21 C.F.R. § 17.23(a) and my January 13, 2017 APHO;
- File a response to CTP's April 7, 2017 Motion to Compel Discovery in accordance with 21 C.F.R. § 17.32(a) and my April 11, 2017 Order;
- Comply with my May 11, 2017 Order to Compel Discovery requiring a response by May 19, 2017; and
- Comply with my June 16, 2017 Order, extending the Discovery response deadline until June 23, 2017.

I find that Respondent has failed to comply with four judicial orders, has failed to defend its case, and has interfered with the speedy, orderly, and fair conduct of this proceeding. I therefore grant CTP's Motion to Impose Sanctions. 21 C.F.R. § 17.35(a)(1)-(3).

Due to Respondent's noncompliance, 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). 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). I find Respondent's repeated failure to comply is more than sufficiently egregious to warrant striking the answer and issue a decision by default, without further proceedings. 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 December 11, 2015, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2015-H-4494, against Respondent for four violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's business establishment, 200 North State Street, Clarks Summit, Pennsylvania 18411, on February 28, 2014, and August 25, 2015;¹
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- At approximately 3:23 PM on April 27, 2016, at Respondent's business establishment, 200 North State Street, Clarks Summit, Pennsylvania 18411, 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;
- At an unspecified time on May 3, 2016, at Respondent's business establishment, 200 North State Street, Clarks Summit, Pennsylvania 18411, an FDA-commissioned inspector observed customer-accessible shelves located throughout the main sales floor of the establishment containing multiple varieties of smokeless tobacco and cigarette tobacco, including but not limited to Red Man smokeless tobacco, Bugler Gold cigarette tobacco, and Gambler Tube Cut Full Flavor cigarette tobacco. On April 27, 2016, a person younger than 18 years of age was able to enter the establishment and purchase a tobacco product. Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

¹ An FDA-commissioned inspector documented one violation on February 28, 2014 (using a self-service display in a non-exempt facility), and three violations on August 25, 2015 (sale to a minor, failure to verify through photographic identification, and using a self-service display in a non-exempt facility).

These facts establish Respondent Summit Cigar'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); 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 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 tobacco product purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.16(c), no retailer may utilize a self-service display in a facility where a person younger than 18 years of age is present or permitted to enter.

Under 21 C.F.R. § 17.2, an \$11,002 civil money penalty is permissible for seven violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$11,002 against Respondent FC and G, Inc. d/b/a Summit Cigar. 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

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