

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-3344)

Complainant,

v.

Fort Ave Investments, LLC
d/b/a Garden Restaurant and Lounge,

Respondent.

Docket No. C-15-4137

Decision No. CR4572

Date: April 7, 2016

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Fort Ave Investments, LLC d/b/a Garden Restaurant and Lounge, at 1501 Light Street, Baltimore, Maryland 21230, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Garden Restaurant and Lounge impermissibly sold cigarettes to minors, on two separate occasions, 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 \$250 civil money penalty against Respondent Garden Restaurant and Lounge. During the hearing process, Respondent failed to comply with two judicial directions regarding discovery requests. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

Respondent timely answered CTP's complaint. Administrative Law Judge Margaret G. Brakebusch issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the December 31, 2015 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 December 30, 2015. On February 4, 2016, CTP filed a motion to compel discovery indicating that CTP had not received a response to its request. *See* 21 C.F.R. § 17.23(a). On February 4, 2016, CTP also filed a motion to extend deadlines. On January 27, 2016, the case was reassigned to Administrative Law Judge Steven T. Kessel. Pursuant to Judge Kessel's direction, a February 19, 2016 letter allowed Respondent until March 4, 2016 to file a response to CTP's motion to compel discovery. On February 19, 2016, Judge Kessel also issued an Order that extended the parties' pre-hearing exchange deadlines.

On March 9, 2016, CTP filed an updated status report requesting that its motion to compel discovery be granted and that deadlines applicable to CTP be extended. The updated status report stated that Respondent had not objected to CTP's motion to compel discovery or produced any documents responsive to CTP's request for production of documents.

On March 10, 2016, Judge Kessel issued an Order that granted CTP's motion to compel discovery. In that Order, Judge Kessel stated that Respondent shall comply with CTP's request for production of documents by March 30, 2016. Judge Kessel further stated 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. Within five (5) days of Respondent's deadline to comply with discovery, CTP must file a status report notifying me whether Respondent has complied with discovery.

The March 10, 2016 Order also further extended the parties' pre-hearing exchange deadlines.

On April 1, 2016, CTP filed a motion to extend deadlines. On April 1, 2016, CTP also filed a status report and a motion to impose sanctions advising that Respondent had not complied with Judge Kessel's March 10, 2016 Order and asking that Respondent's answer be stricken and that a default judgment be issued in this case. On April 4, 2016, this case was reassigned to me.

I. Striking Respondent's Answer

Respondent has failed to comply with the Acknowledgment and Pre-Hearing Order that required a timely response to discovery requests, and Respondent has failed to comply with the Order compelling discovery responses to be provided by March 30, 2016. Respondent did not comply with any of CTP's discovery requests. In addition, Respondent did not respond to CTP's motion to compel, despite being given the opportunity to do so. Respondent has not made any contact with this court since October 28, 2015, the date Respondent timely filed its answer. Respondent's failure to effectively prosecute and defend actions taken over the course of the proceedings have interfered with the orderly and speedy processing of this case, further warranting imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's failure to comply with the Acknowledgment and Pre-Hearing Order, and Respondent's failure to comply with the Order compelling discovery responses, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. § 17.35(c) (3), 17.11(a).¹ The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b). Respondent did not comply with the order nor did it provide any adequate justification for not doing so.

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:

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 28, 2015, CTP served the complaint on Respondent Garden Restaurant and Lounge by United Parcel Service.

¹ As I am issuing a default decision, it is unnecessary to rule on CTP's April 1, 2016 motion to extend deadlines.

- At approximately 12:31 p.m. on January 16, 2015, at Respondent's business establishment, 1501 Light Street, Baltimore, Maryland 21230, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age;
- In a warning letter dated March 6, 2015, CTP informed Respondent of the inspector's January 16, 2015 observation, and that such action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 12:48 p.m. on May 20, 2015, at Respondent's business establishment, 1501 Light Street, Baltimore, Maryland 21230, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent Garden Restaurant and Lounge'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), no retailer may sell cigarettes to any person younger than 18 years of age.

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Fort Ave Investments, LLC d/b/a Garden Restaurant and Lounge. 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