

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2179)

Complainant

v.

Guirey, Inc. / Amy Guirey
d/b/a Village Pub,

Respondent.

Docket No. C-15-659

Decision No. CR3892

Date: May 26, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Guirey, Inc. / Amy Guirey, d/b/a Village Pub, at 411 Mill Street, Ortonville, Michigan 48462, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Village Pub impermissibly 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 \$250 civil money penalty against Respondent Village Pub. Respondent has failed to comply with judicial directions to comply with discovery requests. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

The Respondent timely filed an answer to CTP's complaint on January 16, 2015. I issued an Acknowledgement and Prehearing Order (APHO) on February 2, 2015, that set deadlines for parties' submissions, including the March 2, 2015 deadline to request that

the opposing party provide copies of documents relevant to this case. The APHO further stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. Also, item #16 "Sanctions for failure to comply with orders," stated that these included but were not limited to the dismissal of the complaint or answer if a party failed to comply with any order.

CTP served Respondent with its request for documents on March 2, 2015. On April 14, 2015, CTP filed a Motion to Compel Discovery, requesting "that an order be entered to require Respondent to comply with the Request for Production of Documents in its entirety." CTP also moved to hold deadlines in abeyance, citing the need for "sufficient time to review the requested documents."

On April 24, 2015, I advised both parties that the Respondent had until May 1, 2015 to either comply with discovery requests or file a Motion for Protective Order. I further advised that failure to do so could 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.

On May 8, 2015, I ordered Respondent to either comply with CTP's Request for Production of Documents, or provide satisfactory explanation showing good cause for its failure to comply with the request, by May 15, 2015. I also reiterated that noncompliance may result in sanctions, including dismissal of Respondent's request for hearing and 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. To date, Respondent has failed to comply with discovery requests.

II. Striking Respondent's Answer

Respondent has neither complied with discovery requests, nor provided any explanation for noncompliance, despite being ordered to do so. On April 24, 2015, I directed Respondent to either comply with discovery requests or file a Motion for Protective Order. Then on May 8, 2015, I ordered Respondent to either comply with discovery requests, or provide satisfactory explanation for its noncompliance. Along with both of these judicial directions, I informed Respondent that noncompliance could result in an effective dismissal of this case.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or noncompliance, and I find Respondent's failure to comply with discovery requests sufficient to warrant striking the answer and issuing a decision. 21 C.F.R. § 17.35. I hereby strike Respondent's answer, and assume the facts alleged in CTP's complaint to be true. See 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. 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 that default judgment is merited based on the allegations of the complaint. 21 C.F.R. § 17.11. Specifically:

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 17, 2014, CTP served the complaint on Respondent Village Pub by United Parcel Service.

- Respondent owns Village Pub, an establishment that sells tobacco products and is located at 411 Mill Street, Ortonville, Michigan 48462. Complaint ¶ 2.
- During an inspection of Respondent's establishment on April 3, 2014, an FDA-commissioned inspector observed "a cigarette vending machine in the establishment and was told by the bartender on duty that minors are allowed to enter until 9:00 PM or with a parent or guardian." Complaint ¶ 10.
- On May 8, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from April 3, 2014. The letter explained that the observation constituted a violation of the regulation found at 21 C.F.R. § 1140.14(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- Amy Guirey responded to the Warning Letter in a May 22, 2014 email. "Ms. Guirey stated that the vending machine 'was equipped with a device that must be activated by staff after a request is made and proper identification shown.' On June 11, 2014, by telephone, upon learning that the lockout device described in her response letter was insufficient to satisfy the requirements of the Act, Ms. Guirey indicated that the vending machine would be removed from Village Pub." Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment on July 21 and 30, 2014, an FDA-commissioned inspector observed "a cigarette vending machine in the establishment and was told by an employee that minors are permitted to enter when accompanied by an adult." Complaint ¶ 1.

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 distributed or offered for sale in any state 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). The regulations provide that a retailer may sell cigarettes or smokeless tobacco only in direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine), 21 C.F.R. § 1140.14(c), except where no person younger than 18 years of age is present in or allowed to enter the establishment at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent violated the prohibition against using a vending machine in a non-exempt facility, 21 C.F.R. § 1140.14(c), on April 3, 2014, and July 21 and 30, 2014. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge