

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-0726)

Complainant

v.

Gill Investments Marathon LLC
d/b/a Marathon,

Respondent.

Docket No. T-16-366

Decision No. TB741

Date: January 13, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Gill Investments Marathon LLC d/b/a Marathon, located at 4720 West 56th Street, Indianapolis, Indiana 46254, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Marathon impermissibly sold cigarettes 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. CTP seeks to impose a \$500 civil money penalty against Respondent Marathon. During the hearing process, Respondent has failed to comply with three separate judicial directions regarding CTP's discovery request. I therefore 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 \$500 civil money penalty, on Respondent Gill Investments Marathon LLC d/b/a Marathon, at 4720 West 56th Street, Indianapolis, Indiana 46254. Respondent filed an answer to CTP's complaint on June 3, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on June 16, 2016, that set deadlines for parties' submissions, including the July 20, 2016 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 July 19, 2016.

On August 29, 2016, 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 requesting that all pre-hearing exchange deadlines be extended for 30 days. In a letter issued by my direction, Respondent was given until September 15, 2016, to object to CTP's motion. Respondent did not file an objection to CTP's motion. On September 29, 2016, CTP filed an Updated Status Report indicating that Respondent had not produced any documents.

In an October 3, 2016 Order, I granted CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines. The Order allowed Respondent until October 18, 2016 to comply with CTP's discovery request. In granting CTP's Motion to Compel Discovery, I explained that failure to comply with CTP's discovery request 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. CTP subsequently filed a Motion to Impose Sanctions on October 26, 2016, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. In a November 3, 2016 letter issued by my direction, Respondent was given until November 16, 2016, to object to CTP's motion. On November 28, 2016, CTP filed an Updated Status Report and Motion to Extend Deadlines requesting that I grant its Motion to Impose Sanctions and extend the pre-hearing exchange deadlines.

On December 4, 2016, Respondent emailed Counsel for Respondent indicating that he had received the Updated Status Report and Motion to Extend Deadlines. Respondent stated that "I have not produced any documents since I don't feel that I should have to produce them. It is the FDA that is claiming we sold tobacco product [sic] to a minor but has not proved [sic] it." In a December 6, 2016 letter issued by my direction, Respondent was given until December 16, 2016 to produce the documents that CTP had requested. In the December 6, 2016 letter, I reminded Respondent "that failure to respond to motions and orders 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.” In the December 6, 2016 letter, I also extended the pre-exchange deadlines for each party for 30 days. On December 27, 2016, CTP filed an Updated Status Report indicating that Respondent had not produced any documents.

II. Striking Respondent’s Answer

On October 26, 2016, CTP filed a Motion to Impose Sanctions. In its October 26, 2016 Motion for Sanctions, CTP stated that “Respondent has neither produced any of the requested documents nor contacted Complainant or its Counsel regarding this matter.” Respondent filed no response to CTP’s motion.

Due to noncompliance with my Acknowledgement and Pre-Hearing Order (APHO), my Order granting CTP’s Motion to Compel, and my December 6, 2016 letter ordering production of documents, 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(a)(1), 17.35(c) (3), 17.11(a). 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).

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:

- Respondent owns Marathon, an establishment that sells tobacco products and is located at 4720 West 56th Street, Indianapolis, Indiana 46254. Complaint ¶¶ 6-7.
- During an inspection of Respondent’s establishment on February 21, 2014, at approximately 8:15 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On April 24, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 21, 2014. The letter explained that the

observations constituted violations of regulations, and that the named violations were 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10-11.

- During a subsequent inspection of Respondent’s establishment on November 7, 2015, at approximately 1:27 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 8.

These facts establish Respondent Marathon’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 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); 81 Fed Reg. 28,974, 28975-76 (May 10, 2016). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on February 21, 2014, and November 7, 2015. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Gill Investments Marathon LLC d/b/a Marathon. 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/
Steven T. Kessel
Administrative Law Judge