Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2017-H-3116)

Complainant

v.

Tower Petroleum Corporation d/b/a Marathon,

Respondent.

Docket No. T-17-4275

Decision No. TB2322

Date: December 21, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Tower Petroleum Corporation d/b/a Marathon, at 20020 West 8 Mile Road, Southfield, Michigan 48075, 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 tobacco products 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 Respondent Marathon previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, has now committed a total of four violations of 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, within a twenty-four month period. Therefore, CTP seeks to impose a \$2,236 civil money penalty against Respondent Marathon. During the hearing process, Respondent has failed to comply

with two judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

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I. <u>Background and Procedural History</u>

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 30, 2017, CTP served the complaint on Respondent Marathon by United Parcel Service. On July 3, 2017, Respondent timely filed an answer.¹ In its answer, Respondent denied the allegations in the Complaint, described efforts to avoid selling tobacco to minors, and stated that the penalty was too high. *See* Answer at 1-2. On July 20, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) acknowledging receipt of Respondent's answer and establishing procedural deadlines for this case.

On August 3, 2017, Respondent filed an informal brief (Respondent's Brief). In the brief, Respondent admitted to the violations as alleged in the complaint. Respondent's Brief at 4. On August 10, 2017, CTP filed a Motion for Partial Summary Decision on the grounds that Respondent has admitted the alleged violations in the Complaint, and only disputes the civil money penalty amount. Therefore, CTP requested that I "enter partial summary decision in CTP's favor on liability, leaving for resolution only the amount of the civil money penalty to be imposed." Motion for Partial Summary Decision at 2. In an August 16, 2017 letter written at my direction, Respondent was given until September 11, 2017, to file a Response to CTP's Motion. On September 8, 2017, Respondent filed a response to CTP's Motion and also requested that I enter partial summary decision in its favor. On September 11, 2017, CTP filed an opposition to Respondent's request for partial summary decision.

In an order dated September 22, 2017, I granted CTP's Motion for Partial Summary Decision and found that Respondent committed four violations of the Act and its implementing regulations within a twenty-four month period. I advised the parties that when determining the amount of a civil money penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 333(f)(5)(B); see September 22, 2017 Order at 5. Therefore, I gave the parties an opportunity to present evidence on the appropriateness of the amount of civil money penalty sought by CTP. I ordered Respondent to respond to CTP's Request for Production of Documents by October 9, 2017 and ordered the parties to file pre-hearing exchanges regarding the appropriateness of the civil money penalty amount. CTP's pre-

¹ On June 27, 2017, Respondent filed its Certificate of Service via DAB E-FILE. Respondent subsequently filed its Answer on July 3, 2017. Because of the date of the initial filing, I accepted Respondent's Answer as timely.

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hearing exchange was due on October 31, 2017, and Respondent's was due on November 22, 2017.

On October 16, 2017, CTP filed a Motion to Compel Discovery, requesting "that the ALJ enter an order compelling Respondent to produce all documents responsive to CTP's RFP." CTP's Motion to Compel Discovery states that it has not received a response to its Request for Production of Documents.

In an October 23, 2017 letter, Respondent was given until November 3, 2017, to file a response to CTP's Motion to Compel Discovery. On November 6, 2017, CTP filed a Status Report Concerning CTP's Motion to Compel Discovery stating that "Respondent produced twelve pages of documents, but failed to produce any documents responsive to RFP Requests 2, 8, and 9." Status Report at 2. On November 10, 2017, Respondent filed a response indicating that it had already uploaded a video responsive to RFP Request 2 into the DABACTS system under docket number 13a. Respondent did not address RFP Requests 8 and 9.

In an order dated November 14, 2017, I granted CTP's Motion to Compel Discovery and ordered Respondent to fully comply with CTP's Request for Production of Documents by November 20, 2017. Specifically, Respondent was ordered to produce documents responsive to RFP Requests 2, 8, and 9. Respondent was warned that failure to timely deliver the balance of the requested documents may result in sanctions, including the issuance of an Initial Decision and Default Judgment imposing a civil money penalty.

On November 21, 2017, CTP filed a Motion to Impose Sanctions and Enter Default Judgment indicating that Respondent has not complied with my November 14, 2017 order. CTP requests that I enter a default judgment Respondent and impose a civil money penalty of \$2,236. In a November 24, 2017 letter issued by my direction, Respondent was given until December 7, 2017 to file a response to CTP's Motion to Impose Sanctions. On December 6, 2017, Respondent filed a response but failed to address CTP's motion and failed to explain why it has not complied with my November 14, 2017 order. I note that Respondent asked for an opportunity to present its case at a prehearing conference, and mentioned that CTP's "count of the number of violation[s]" hurts its "small business the most." December 6, 2017 Response. On December 8, 2017, CTP filed a reply to Respondent's response indicating that Respondent, "has not produced any additional documents responsive to Request 2, and it has not produced any documents responsive to Requests 8 and 9."

On December 12, 2017, Respondent filed another response stating, "the documents Requested #8 by the CTP is business personal information that is irrelevant to this case." CTP's RFP Request 8 seeks "[d]ocuments, such as federal and/or state tax returns, sufficient to identify Respondent's reported income for 2016." December 12, 2017 Response. Respondent further stated that it does not understand # 9 requests and

reiterated that "the main issue in the settlement is the number of count of violation" *Id*.

As indicated above, Respondent has admitted to the violations in the complaint, and the only remaining issue is the appropriateness of the amount of civil money penalty sought by CTP. Respondent's argument regarding CTP's method of determining the number of violations has no merit. CTP's computation of the violations was in accordance with regulatory requirements and Respondent has no right to a hearing on this issue. Documents related to Respondent's reported income for 2016 are relevant as they contain information necessary for me to make a decision on the appropriateness of the amount of civil money penalty. Respondent has failed to comply with my November 14, 2017 order and produce these documents as ordered.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions and Enter Default Judgment, and striking Respondent's answer for failing to comply with two judicial directions, specifically the September 22, 2017 order requiring Respondent to respond to CTP's Request for Production of Documents and the November 14, 2017 order granting CTP's motion to compel discovery. This conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

II. <u>Default Decision</u>

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- On December 1, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-905, FDA Docket Number FDA-2016-H-4013, against Respondent for three² 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, 20020 West 8 Mile Road, Southfield, Michigan 48075, on December 12, 2015, and May 11, 2016;
- 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";

² Two violations were documented on December 12, 2015, and two on May 11, 2016. 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.

• At approximately 5:08 p.m. on February 9, 2017, at Respondent's business establishment, 20020 West 8 Mile Road, Southfield, Michigan 48075, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age.

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 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, 28975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1)³, 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. § 17.2, a \$2,236 civil money penalty is permissible for four violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$2,236 against Respondent Tower Petroleum Corporation 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/
Catherine Ravinski
Administrative Law Judge

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.

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