Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Civil Remedies Division

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

Complainant

v.

Tower Petroleum Corporation d/b/a Marathon,

Respondent.

Docket No. T-17-4275

Ruling No. 2017-T-2

Date: September 22, 2017

ORDER

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Tower Petroleum Corporation d/b/a Marathon, 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.

I. Background and Procedural History

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 ("Respondent's Answer"). ¹

In its Answer, Respondent stated that the cashier did not calculate the day and month displayed by the minor's identification because his was distracted by the inspector, whom the cashier was watching to ensure that he did not steal. Respondent's Answer at 1. On July 20, 2017, I issued an order acknowledging receipt of the answer and establishing procedural deadlines for this case.

2

On August 3, 2017, Respondent filed an informal brief (Respondent's Brief). In the brief, Respondent admitted that it sold tobacco products to a minor on February 9, 2017, at approximately 5:08 PM. Respondent stated that the "[c]a[s]hier sold cig[arettes] to [a] minor after checking the minor['s] ID for approximatel[y] 30 sec[onds and] got co[]nfused with calculating the month [and] birth." 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 requests 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.

On September 8, 2017, CTP filed a Notice of Refused Delivery of Complainant's Request for Production of Documents. CTP stated that Respondent refused delivery of CTP's Request for Production of Documents (RFP).

Also on September 8, 2017, Respondent filed a response to CTP's Motion for Partial Summary Decision. Respondent argued that the cashier checked the minor's identification, and that CTP counted the inspection on May 11, 2016, as two violations. Respondent also emphasized that it has made important steps to prevent future violations. Furthermore, Respondent requested that I "enter [a] Partial Summary Decision in Respondent's favor to continue affording and to stay in business capable to hire responsible workers."

On September 11, 2017, CTP filed a response in opposition to Respondent's Motion for Partial Summary Decision.

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.

1

On September 14, 2017, Respondent filed a response to the notice of failed delivery. On September 15, 2017, CTP filed an Unopposed Motion to Extend Deadlines. In the motion, CTP stated that it had originally sent the RFP to the address Respondent provided in its answer. Respondent re-sent the RFP on September 8, 2017, to both the address provided in Respondent's answer, and to Respondent's business location. CTP requested "that the deadline for Respondent to respond to CTP's RFP be extended to October 9, 2017; the due date for CTP's pre-hearing exchange be extended to October 31, 2017; and the due date for Respondent's pre-hearing exchange be extended to November 22, 2017." Unopposed Motion to Extend Deadlines at 2.

3

II. CTP's Motion for Partial Summary Decision

I have the authority to grant a motion for a summary decision if "the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b). The material facts in this case are undisputed. Specifically:

- On December 1, 2016, CTP initiated the first 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. Complaint ¶ 11.
- The first Civil Money Penalty 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." Complaint ¶ 12.
- 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. Complaint ¶9.

² Two violations were documented on December 12, 2015 (sale to a minor and failure to check identification), and two on May 11, 2016 (sale to a minor and failure to check identification). 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.

-

These facts establish Respondent Marathon's liability under the Act and CTP is entitled to partial summary decision as a matter of law. 21 C.F.R. § 17.17(b). 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)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.

Respondent has failed in its pleadings to establish a genuine issue as to any material fact. Respondent has admitted to selling a tobacco product to a minor. Respondent's Brief at 4. Respondent's arguments that the cashier was distracted or confused by the identification are unpersuasive. Furthermore, Respondent's argument that the two violations on May 11, 2016, should only be counted as one violation is erroneous as a matter of law. CTP's method of counting violations is based on a reasonable and permissible interpretation of the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations. See Orton Motor Company, d/b/a Orton's Bagley, DAB No. 2717 (2016).

A partial summary decision is appropriate here because the facts of this case are undisputed and Respondent is liable, under the Act, for the violations as alleged in the Complaint. CTP's Motion for Partial Summary Decision is hereby **GRANTED**.

III. Respondent's Motion for Partial Summary Decision

Respondent has failed to establish grounds for a partial summary decision in its favor. Respondent's Motion for Partial Summary Decision is hereby **DENIED**.

IV. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Marathon is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP seeks to impose the penalty amount of \$2,236, against Respondent for four violations of the Act and its implementing regulations within a twenty-four month period.

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

•

I find that Respondent committed four violations of the Act and its implementing regulations within a twenty-four month period. 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). As a result of my liability determination, I find that a final decision on the record with regard to that issue is appropriate in this matter. Accordingly, I will now give the parties the opportunity to present evidence on the appropriateness of the amount of Civil Money Penalty.

V. Unopposed Motion to Extend Deadlines

I find good cause to extend the procedural deadlines, and hereby grant the Unopposed Motion to Extend Deadlines. Respondent shall have until **October 9, 2017**, to respond to CTP's Request for Production of Documents. The due date for CTP's pre-hearing exchange regarding the appropriateness of the civil money penalty amount is **October 31, 2017**. The due date for Respondent's pre-hearing exchange regarding the appropriateness of the civil money penalty amount is **November 22, 2017**. I will consider all arguments made by Respondent in its Answer and informal brief when determining the appropriateness of the civil money penalty amount. Respondent may file a supplement to its informal brief to address any new arguments made by CTP in its pre-hearing exchange. Respondent may also file any material evidence it would like me to consider when making a determination about the civil money penalty amount.

IT IS SO ORDERED.

/s/

Catherine Ravinski Administrative Law Judge