

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

Center for Tobacco Products,

Complainant

v.

Orton Motor, Inc.
d/b/a Orton's Park Rapids West,

Respondent.

Docket No. T-17-2243
FDA Docket No. FDA-2017-H-0858

Decision No. TB2257

Date: November 29, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Orton Motor, Inc. d/b/a Orton's Park Rapids West, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$550. For the reasons outlined below, I enter judgment against Respondent and assess a civil money penalty of \$550.

I. Procedural History.

On February 22, 2017, CTP served its Complaint on Respondent by United Parcel Service (UPS), pursuant to 21 C.F.R. §§ 17.5 and 17.7. It asserted that Respondent impermissibly sold cigarettes to minors and failed to verify that cigarette purchasers were 18 years of age or older, in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations found at 21 C.F.R. pt. 1140.

CTP seeks a civil money penalty of \$550. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty,

file an answer, or request an extension within which to file an answer. Respondent filed its Answer on March 23, 2017.

On March 29, 2017, I issued an Acknowledgment and Pre-Hearing Order which established a schedule to regulate the course of discovery and the parties' submission of evidence and arguments. On June 5, 2017, CTP filed a Motion to Compel Discovery, asserting Respondent had not responded to its timely served document production requests. I gave Respondent until June 21, 2017 to file a response to CTP's motion to compel, to which Respondent failed to respond.

On June 22, 2017, I issued an Order granting CTP's Motion to Compel Discovery and instructing Respondent to comply with CTP's Request for Production of Documents by July 7, 2017. In the Order, I warned Respondent that failure to respond could result in the imposition of sanctions, including the issuance of an Initial Decision and Default Judgment.

On June 30, 2017, CTP filed Stipulations of Fact signed by representatives of both parties. In the Stipulations of Fact, the parties agreed that the violations occurred as CTP alleged on July 14, 2015 and September 14, 2016. Respondent further conceded that it had the means to pay the \$550 civil money penalty sought by CTP.

CTP also filed a Motion for Summary Decision on that date. On August 16, 2017, Respondent filed a response to CTP's Motion (Response) reiterating it did not dispute the allegations made by CTP, and maintaining it had the ability to pay the monetary penalty sought by CTP. *See* Response. Respondent clarified that it instead disagreed with CTP's application of the law, and asked that I stay this matter pending the outcome of a related case in federal district court, to which it had appealed a Departmental Appeals Board decision affirming the legality of CTP's interpretation as to the counting of violations during inspections. *See Orton Motor Co., d/b/a Orton's Bagley*, DAB Decision No. 2717 (Jun. 30, 2016).

In my Order dated September 8, 2017, I denied Respondent's request to stay the proceedings, concluding that ". . . [u]ntil a court of competent jurisdiction overrules [the related case], the Board's determination . . . is precedential and binding on any decision I make."

II. A Decision on the Record Is Appropriate.

CTP has sought summary decision in this matter, asserting there is no genuine issue of material of fact and that CTP is entitled to judgment in its favor. *See* Motion at 2. Under 21 C.F.R. § 17.17(b), summary decision is appropriate if the pleadings, affidavits, and other materials filed in the record show that there is no genuine issue of material fact and the moving party is entitled to summary decision as a matter of law.

Here, neither party has indicated a hearing is necessary in this matter or objected to the submissions of the other party. Instead, Respondent has conceded, in both the Stipulation of Facts and in its response to CTP's Motion, that the violations for which CTP seeks a money penalty occurred as alleged in CTP's Complaint. Consequently, I receive the parties' written exchanges and exhibits into evidence and will decide this case based on the administrative record.

III. Discussion.

Because Respondent explicitly concedes that the allegations made in CTP's Complaint are not in dispute, I find the record establishes by preponderance of the evidence that:

- Respondent owns Orton's Park Rapids West, an establishment that sells tobacco products and is located at 100 Park Avenue South, Park Rapids, Minnesota 56470. Complaint ¶¶ 6-7.
- During an inspection of Respondent's establishment on July 14, 2015, at approximately 1:05 PM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” *Id.* at ¶ 10.
- On August 6, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's documented violation from July 14, 2015. The letter explained that the documented violation constituted a violation of regulations, 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. *Id.* at 10-11.
- During a subsequent inspection of Respondent's establishment on September 14, 2016, at approximately 11:21 AM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspector also documented that "the minor's identification was not verified before the sale” *Id.* at ¶ 8.

These facts establish that Respondent is liable under the Act, which 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 applicable regulations prohibit the sale of cigarettes to any person younger than 18 years of age, and 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)(1), 1140.14(a)(2)(i).

I find Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on July 14, 2015, and September 14, 2016. On September 14, 2016, 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.

Respondent has conceded it is able to pay the penalty amount sought by CTP, and that it would not constitute a financial hardship to pay that amount. Respondent has not argued the penalty amount to be too high, but instead contested the number of violations that occurred within 24 months. Answer at 2. Respondent also failed to submit any evidence that would allow me to consider other mitigating statutory factors. *See* 21 U.S.C. § 333(f)(5)(B). Accordingly, I find the \$550 penalty amount sought by CTP to be appropriate.

ORDER

For these reasons, CTP's Motion for Summary Decision is **GRANTED** and I enter judgment in the amount of \$550 against Respondent Orton Motor, Inc. d/b/a Orton's Park Rapids West. 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/
Bill Thomas
Administrative Law Judge