Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2015-H-4482)

Complainant

v.

Lincoln Land Auto Parts LLC d/b/a Patriot Station Service Center,

Respondent.

Docket No. T-16-1681

Decision No. TB235

Date: September 21, 2016

INITIAL DECISION

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Lincoln Land Auto Parts LLC, d/b/a Patriot Station Service Center, at 6957 East State Road 62, Mariah Hill, Indiana 47556 (Respondent), and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent 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 previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent.

On December 9, 2015, CTP served the complaint on Respondent by United Parcel Service. Respondent filed an Answer on December 9, 2015. The parties subsequently filed a Joint Motion to Stay the Proceedings and the matter was stayed until July 8, 2016.

On April 20, 2016, the parties filed Stipulations of Fact. In the Stipulations of Fact, which were signed by a representative for Respondent, the parties agreed that the violations occurred as alleged on August 22, 2015. Respondent further agreed that it had the means to pay the civil money penalty.

On August 1, 2016, CTP filed a Motion for Summary Decision. Judge Booker, to whom this case was previously assigned, gave Respondent until August 16, 2016 to respond. As of today's date, Respondent has not filed a response to the Motion for Summary Decision, nor has it sought additional time to file one.

Under 21 C.F.R. § 17.17(b), summary decision shall be granted if the pleadings, affidavits, and other materials filed in the record show that there is no genuine issue of material fact and that the party is entitled to summary decision as a matter of law. Here, Respondent has not filed a response contesting the facts asserted in the CTP's Motion for Summary Decision. Moreover, Respondent has signed a stipulation agreeing that the violations occurred as alleged.

As a result, I find the following:

- On February 5, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-1151, FDA Docket Number FDA-2015-H-0327, against Respondent for three¹ 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, 6957 East State Road 62, Mariah Hill, Indiana 47556, on September 21, 2013, and August 23, 2014;
- The previous action concluded when Respondent admitted all of the allegations in the Complaint and paid the agreed upon penalty. Further, Respondent expressly waived its right to contest such violations in subsequent actions.
- At approximately 8:32 a.m. on August 22, 2015, at Respondent's business establishment, 6957 East State Road 62, Mariah Hill, Indiana 47556, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic

¹ One violation was documented on September 21, 2013, and two on August 23, 2014. In accordance with customary practice, CTP counted any violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent'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. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), 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 \$5,000 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

ORDER

For these reasons, CTP's Motion for Summary Decision is Granted and I enter judgment in the amount of \$5,000 against Respondent Lincoln Land Auto Parts LLC, d/b/a Patriot Station Service Center.

/s/

Bill Thomas Administrative Law Judge