

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

RG Service, Corp.
d/b/a Puma,

Respondent.

Docket No. T-17-2685
FDA Docket No. FDA-2017-H-1363

Decision No. TB1542

Date: June 27, 2017

**INITIAL DECISION GRANTING COMPLAINANT'S MOTION FOR
SUMMARY DECISION AND IMPOSING CIVIL MONEY PENALTY**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, RG Service, Corp. d/b/a Puma, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$275. CTP has filed a Motion for Summary Decision. I find that there is no genuine issue as to any material fact and Complainant is entitled to summary decision as a matter of law. Therefore, I enter summary decision against Respondent and assess a civil money penalty of \$275.

I. Background

CTP began this case by serving the Complaint on Respondent and 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 cigarettes to minors and failed to verify that cigarette 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$275.

On March 17, 2017, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. On April 11, 2017, Respondent timely filed an Answer. In its Answer, Respondent admitted all of the allegations made in the Complaint, raised no defenses, and agreed that the \$275 civil money penalty sought is appropriate. On April 18, 2017, I issued an Acknowledgment and Pre-hearing Order (Order) that set out instructions regarding a motion for summary decision and an opposition to a motion for summary decision. *See* Order ¶¶ 13-14. On May 5, 2017, CTP filed a Motion for Summary Decision pursuant to 21 C.F.R. § 17.17 and paragraphs 13 and 14 of the April 18, 2017 Order. On May 19, 2017, I gave Respondent until June 19, 2017, to file a response to CTP's Motion for Summary Judgment. Respondent did not respond to CTP's Motion for Summary Decision within the allotted time.

II. Discussion

Under 21 C.F.R. § 17.17(b), I have the authority to grant a motion for summary decision 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 contested the facts asserted in the CTP's Motion for Summary Decision. Moreover, Respondent admitted all of the allegations in the Complaint, offered no defense to liability, and agreed that the \$275 civil money penalty is appropriate.

As a result, I find the following:

- Respondent owns Puma, an establishment that sells tobacco products and is located at Carr. 102 Int. Carr. 103, Sect. Coqui, Cabo Rojo, Puerto Rico 00623. Complaint ¶¶ 5-6.
- During an inspection of Respondent's establishment on April 29, 2016, at approximately 5:57 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]" The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 9.
- On May 12, 2016, CTP issued a Warning Letter to Respondent regarding the inspector's observations from April 29, 2016. 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 ¶¶ 9-10.

- During a subsequent inspection of Respondent's establishment on September 27, 2016, at approximately 7:20 PM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . [.]” Complaint ¶ 7.

These facts establish that Respondent is liable 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, 28,975-76 (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 April 29, 2016, and September 27, 2016. On April 29, 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.

For these reasons, CTP's Motion for Summary Decision is GRANTED. CTP has requested a civil money penalty of \$275, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$275 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge