

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

MGGDGM LLC
d/b/a Kountry Korner,

Respondent.

Docket No. C-15-64
FDA Docket No. FDA-2014-H-1555

Decision No. CR3489

Date: December 2, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, MGGDGM LLC d/b/a Kountry Korner, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$250.

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, 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 (2013). CTP seeks a civil money penalty of \$250.

On October 16, 2014, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. 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 of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Kountry Korner, an establishment that sells tobacco products and is located at 49017 Morris Road, Hammond, Louisiana 70401. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on October 18, 2013, at approximately 6:13 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro Silver Pack cigarettes . . . [.]” Complaint ¶ 10.
- On December 26, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from October 18, 2013. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), 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. Complaint ¶ 10.
- Patricia Prevost, Respondent’s establishment’s manager, responded to the Warning Letter in a January 1, 2014 letter. “Ms. Prevost stated that she took disciplinary action against the stated employee and conducted a training meeting with all employees to make sure all employees are aware of both the laws concerning tobacco sales and the consequences for violating those laws.” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on April 5, 2014, at approximately 3:49 PM, FDA-commissioned inspectors documented that “a

person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes . . . [.]” Complaint ¶ 1.

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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

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), on October 18, 2013, and April 5, 2014. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge