

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

JMG Food Inc.
d/b/a Country Mark / Mobil,

Respondent.

Docket No. C-14-1440
FDA Docket No. FDA-2014-H-0948

Decision No. CR3412

Date: October 8, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, JMG Food Inc. d/b/a Country Mark / Mobil, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

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 smokeless tobacco to minors and failed to verify that a smokeless tobacco purchaser was 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 (2013). CTP seeks a civil money penalty of \$500.

On August 12, 2014, CTP served the Complaint on Respondent¹ 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 Country Mark / Mobil, an establishment that sells tobacco products and is located at 306 West Pat Rady Way, Bainbridge, Indiana 46105. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on July 25, 2012, at approximately 8:46 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Wintergreen smokeless tobacco” Complaint ¶ 10.
- On October 4, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from July 25, 2012. The letter explained that the observation 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.

¹ CTP served Respondent at 3646 Pickwick Circle, Plainfield, Indiana 46168. *See* Proof of Service. CTP alleges that Respondent’s establishment is located, however, at 306 West Pat Rady Way, Bainbridge, Indiana 46105. Complaint ¶ 3. Nevertheless, an individual named “SANHI” signed for the package, which was addressed to Respondent. *See* Proof of Service. Additionally, my office issued an Initial Order Establishing Procedures to both addresses, neither of which was returned as improperly addressed. Therefore, I will infer that Respondent had proper notice in this matter in the absence of any evidence to the contrary.

- Though United Parcel Service records indicate that an individual named “Rich” received the Warning Letter on October 5, 2012, the FDA did not receive a response from Respondent. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on December 11, 2013, at approximately 6:25 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” 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 smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no smokeless tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on July 25, 2012, and December 11, 2013. On December 11, 2013, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no smokeless tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$500, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge