## **Department of Health and Human Services**

## DEPARTMENTAL APPEALS BOARD

## **Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Check Masters, Inc. d/b/a Discount Tobacco Masters,

Respondent.

Docket No. C-15-353 FDA Docket No. FDA-2014-H-1886

Decision No. CR3582

Date: January 20, 2015

## INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Check Masters, Inc. d/b/a Discount Tobacco Masters 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 unlawfully utilized a self-service display of cigarette and smokeless tobacco in a non-exempt facility, impermissibly sold cigarettes to a minor, and failed to verify, by means of photo identification containing a date of birth, that a 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 November 18, 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 Discount Tobacco Masters, an establishment that sells tobacco products and is located at 12 East Broadway Street, Shelbyville, Indiana 46176. Complaint ¶ 3.
- During an inspection of Respondent's establishment on August 22, 2012, at an unspecified time, an FDA-commissioned inspector observed "customer-accessible shelves containing numerous brands of cigarettes, cigarette tobacco and smokeless tobacco on the main sales floor." The inspector also observed that the establishment allows minors to enter during regular business hours. Complaint ¶ 10.
- On November 29, 2012, CTP issued a Warning Letter to Respondent regarding the inspector's observations from August 22, 2012. The letter explained that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.16(c) 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.
- Talmage Thompson responded to the Warning Letter via a December 10, 2012 letter. Mr. Thompson stated that "Respondent posted age restricted signage, moved all smokeless tobacco and 'partial cigarettes product' behind the counter, and reviewed FDA's tobacco website with all employees." Complaint ¶ 11.

• During a subsequent inspection of Respondent's establishment on May 21, 2014, at approximately 4:40 PM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]" The inspector also observed 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 cigarettes 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 cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). The regulations also require a retailer to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange. 21 C.F.R. § 1140.16(c).

Taking the above alleged facts as true, on August 22, 2012 Respondent utilized a self-service display in violation of 21 C.F.R. § 1140.16(c). On May 21, 2014, the Respondent also violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and 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(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