

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

M and F Smoke Shop LLC,

Respondent.

Docket No. C-14-1989  
FDA Docket No. FDA-2014-H-1466

Decision No. CR3465

Date: November 18, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, M and F Smoke Shop LLC 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 used a self-service display in a non-exempt location, impermissibly sold cigarettes to a minor, and failed to verify that a cigarette 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 October 7, 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 M and F Smoke Shop, an establishment that sells tobacco products and is located at 3458 West Van Buren Street, Suite 101, Phoenix, Arizona 85009. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on November 4, 2013, at an unspecified time, an FDA-commissioned inspector observed that the establishment, which was open to minors, “had cigarette tobacco available on shelves in an area of the establishment open to all customers.” Complaint ¶ 10.
- On January 9, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from November 4, 2013. The letter explained that the observation 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent was responsible for complying with the law. Complaint ¶ 10.
- On January 10, 2014, Andrew Hilton, who identified himself as the manager of M and F Smoke Shop, responded to the Warning Letter via telephone. Hilton stated that “the establishment [was] now restricted to customers [18] years of age or older at all times, and that he and the establishment’s staff [would] enforce the new restriction.” Complaint ¶ 11.

- During a subsequent inspection of Respondent's establishment conducted on March 19, 2014, at approximately 10:56 AM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes ... [.]". The inspectors also documented that the "minor's identification was not verified before the sale ...."

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). Moreover, the regulations dictate that a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. 21 C.F.R. § 1140.16(c). A self-service display is a method of sale expressly prohibited by the regulations unless the self-service display is located in a facility in which the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, on November 4, 2013, Respondent violated 21 C.F.R. § 1140.16(c) by utilizing a self-service display to sell regulated tobacco products in a facility that permitted persons younger than 18 years of age to enter. Respondent then violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on March 19, 2014. Finally, on March 19, 2014, 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(b)(1). Respondent's actions thus constitute violations of law that merit a civil money penalty.

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

\_\_\_\_\_  
/s/  
Steven T. Kessel  
Administrative Law Judge