

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2014-H-0580)

Complainant

v.

Al Zama LLC  
d/b/a Smoker's Discount World,

Respondent.

Docket No. C-14-1055

Decision No. CR3290

Date: July 11, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Al Zama LLC d/b/a Smoker's Discount World, at 351 Boston Post Road, North Windham, Connecticut 06256, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Smoker's Discount World impermissibly sold cigarettes to a minor and utilized self-service displays containing cigarette tobacco and smokeless tobacco, violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Smoker's Discount World.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 13, 2014, CTP served the complaint on Respondent Smoker's Discount World by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer. CTP warned Respondent that, if it failed to take one of these

actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent Smoker's Discount World has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- On June 25, 2013, an FDA-commissioned inspector observed customer-accessible shelves of cigarette tobacco and smokeless tobacco on the sales floor of Respondent's business establishment at 351 Boston Post Road, Suite 9, North Windham, Connecticut 06256. One of Respondent's employees also stated that the establishment was open to the public;
- In a warning letter dated August 15, 2013, CTP informed Respondent of the inspector's June 25, 2013 observations, and that self-service displays of tobacco products in non-exempt facilities violate federal law, 21 C.F.R. § 1140.16(c). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 9:44 a.m. on November 19, 2013, at Respondent's business establishment, 351 Boston Post Road, Suite 9, North Windham, Connecticut 06256, FDA-commissioned inspectors documented Respondent's staff selling a package of Top Regular Premium cigarette tobacco to a person younger than 18 years of age. The purchaser was also able to directly access the Top Regular Premium cigarette tobacco from a self-service display.

These facts establish Respondent Smoker's Discount World's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or cigarette tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.16(c), retailers may not use self-service displays to sell cigarette tobacco or smokeless tobacco, except in a facility in which no person younger than 18 years of age is permitted to enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

**Order**

For these reasons, I enter default judgment in the amount of \$500 against Respondent Al Zama LLC d/b/a Smoker's Discount World. Pursuant to 21 C.F.R. § 17.11 (b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

                        /s/                          
Carolyn Cozad Hughes  
Administrative Law Judge