

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2014-H-1561)

Complainant

v.

Jeffrey Lynn Warren  
d/b/a One Stop Bait and Tackle,

Respondent.

Docket No. C-15-70

Decision No. CR3500

Date: December 5, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Jeffrey Lynn Warren d/b/a One Stop Bait and Tackle, at 805 Roland Avenue, Surf City, North Carolina 28445, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that One Stop Bait and Tackle unlawfully utilized a self-service display of cigarette tobacco in a non-exempt facility, thereby 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 \$250 civil money penalty against Respondent One Stop Bait and Tackle.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 16, 2014, CTP served the complaint on Respondent One Stop Bait and Tackle 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 One Stop Bait and Tackle 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:

- At Respondent's business establishment, 805 Roland Avenue, Surf City, North Carolina 28445, on August 24, 2013, at an unspecified time, a FDA-commissioned inspector observed the presence of a self-service display of cigarette tobacco. The inspector also observed that the establishment allows minors to enter during regular business hours;
- In a warning letter dated October 31, 2013, CTP informed Respondent of the inspector's August 24, 2013 observations, and that such actions 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 Respondent's business establishment, 805 Roland Avenue, Surf City, North Carolina 28445, on April 19, 2014, at an unspecified time, FDA-commissioned inspectors documented the presence of a self-service display of cigarette tobacco. The inspector also observed that the establishment allows minors to enter during regular business hours.

These facts establish Respondent One Stop Bait and Tackle'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 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 also require a retailer to sell cigarettes only in a direct, face-to-face exchange. 21 C.F.R. § 1140.16(c).

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

**Order**

For these reasons, I enter default judgment in the amount of \$250 against Respondent Jeffrey Lynn Warren d/b/a One Stop Bait and Tackle. 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/

Catherine Ravinski  
Administrative Law Judge