

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-2306)

Complainant,

v.

Tobacco Hut of West Virginia, LLC and
Gregory A. Carter
d/b/a Tobacco Hut of West Virginia,

Respondent.

Docket No. C -15-796

Decision No. CR3686

Date: March 4, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Tobacco Hut of West Virginia, LLC and Gregory A. Carter d/b/a Tobacco Hut of West Virginia, at 498 Camden Road, Huntington, West Virginia 25704, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent Tobacco Hut of West Virginia unlawfully utilized a self-service display of tobacco products in a non-exempt facility and impermissibly sold cigarettes to a minor, 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. CTP seeks to impose a \$500 civil money penalty against Respondent Tobacco Hut of West Virginia.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 6, 2015, CTP served the complaint on Respondent Tobacco Hut of West Virginia 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 Tobacco Hut of West Virginia 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 unspecified time on May 16, 2013, at Respondent's business establishment, 498 Camden Road, Huntington, West Virginia 25704, an FDA-commissioned inspector observed "displays containing multiple brands of smokeless tobacco for sale located on shelving in areas of the establishment that are open to customers." During the inspection, a store employee informed the inspector that "minors are allowed to enter with an adult;"
- In a warning letter dated June 6, 2013, CTP informed Respondent of the inspector's May 16, 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 approximately 8:43 p.m. on September 11, 2014, at Respondent's business establishment, 498 Camden Road, Huntington, West Virginia 25704, an FDA commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes. The inspector also observed Longhorn and Klondike brands of smokeless tobacco in a customer accessible self-service display on the customer side of the checkout counter. Furthermore, a store employee informed the inspector that minors are allowed to enter if they are accompanied by adults.

These facts establish Respondent Tobacco Hut of West Virginia'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 require a retailer to sell cigarettes only in a direct, face-to-face exchange.

