

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-0136)

Complainant

v.

Hot Box Smoke Shop LLC / Jawad Mustafa,

Respondent.

Docket No. C-15-942

Decision No. CR3717

Date: March 19, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Hot Box Smoke Shop LLC / Jawad Mustafa, at 3246 East Cactus Road, Phoenix, Arizona 85032, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Hot Box Smoke Shop LLC / Jawad Mustafa unlawfully utilized a self-service display of tobacco products 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 Hot Box Smoke Shop LLC / Jawad Mustafa.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 23, 2015, CTP served the complaint on Respondent Hot Box Smoke Shop LLC / Jawad Mustafa 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 Hot Box Smoke Shop LLC / Jawad Mustafa 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 an unspecified time on February 7, 2014, at Respondent's business establishment, 3246 East Cactus Road, Phoenix, Arizona 85032, an FDA--commissioned inspector observed "cigarette tobacco for sale from customer-accessible shelves throughout the sales floor." Additionally, the inspector noted establishment is open to the general public during normal business hours;
- In a warning letter dated April 10, 2014, CTP informed Respondent of the inspector's February 7, 2014, observations, and that such action violates 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 an unspecified time on June 27, 2014, at Respondent's business establishment, 3246 East Cactus Road, Phoenix, Arizona 85032, FDA-commissioned inspectors documented a violation for using a self-service display in a non-exempt facility. Specifically, the establishment had shelves of cigarette tobacco accessible to customers on the main sales floor. The inspectors also documented that a minor was able to enter the establishment and retrieve a tobacco product from the display.

These facts establish Respondent Hot Box Smoke Shop LLC / Jawad Mustafa'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. 21 C.F.R. § 1140.16(c).

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

