

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2015-H-0026)

Complainant,

v.

1103 Semi, Inc. / Thomas Kuruvilla and  
Manny Joseph d/b/a Phillips 66,

Respondent.

Docket No. C-15-823

Decision No. CR3685

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, 1103 Semi, Inc. / Thomas Kuruvilla and Manny Joseph d/b/a Phillips 66, at 1103 West Seminary Avenue, Onarga, Illinois 60955, 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 Phillips 66 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 Phillips 66.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 7, 2015, CTP served the complaint on Respondent Phillips 66 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 Phillips 66 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 10, 2014, at Respondent's business establishment, 1103 West Seminary Avenue, Onarga, Illinois 60955, an FDA-commissioned inspector observed "L&M brand cigarettes for sale on the customer counter." The inspector also observed, "a variety of cigarette tobacco located on shelving in an area of the establishment that was open to customers." The inspector noted that the establishment was open to the general public during business hours;
- In a warning letter dated April 10, 2014, CTP informed Respondent of the inspector's February 10, 2014 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 violation could result in a civil money penalty or other regulatory action;
- At approximately 12:55 p.m. on June 27, 2014, at Respondent's business establishment, 1103 West Seminary Avenue, Onarga, Illinois 60955, an FDA commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Camel Crush Regular Fresh cigarettes. The inspector also observed "a customer-accessible display of smokeless tobacco on the sales counter and a shelving unit, next to the sales counter, containing various brands of cigarette tobacco on the main sales floor." During the inspection the inspector also observed "that the establishment [was] open to customers of all ages."

These facts establish Respondent Phillips 66'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).

The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

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 1103 Semi, Inc. / Thomas Kuruvilla and Manny Joseph d/b/a Phillips 66. 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.

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/s/  
Catherine Ravinski  
Administrative Law Judge