## **Department of Health and Human Services**

## DEPARTMENTAL APPEALS BOARD

#### **Civil Remedies Division**

Center for Tobacco Products, (FDA No. FDA-2014-H-1834)

Complainant

v.

S and B Fuel, Inc. d/b/a Phillips 66,

Respondent.

Docket No. C-15-307

Decision No CR3567

Date: January 8, 2015

# INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, S and B Fuel, Inc. d/b/a Phillips 66, at 4347 South Broadway, St. Louis, Missouri 63111, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Phillips 66 unlawfully sold an individual cigarette to a minor, and failed to verify that a cigarette purchasers was 18 years of age or older, 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. An Administrative Law Judge (ALJ) has previously found Respondent to have committed four violations of regulations found at 21 C.F.R. pt. 1140. *S & B Fuel Inc. d/b/a Phillips 66*, DAB CR3110, at 2-3 (2014); Complaint ¶ 11. Therefore, CTP seeks to impose a \$10,000 civil money penalty against Respondent Phillips 66.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on November 13, 2014, 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 ALJ 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:

- CTP previously issued a warning letter to Respondent Phillips 66 on January 24, 2013, citing a violation<sup>1</sup> of 21 C.F.R. pt. 1140 on December 28, 2012, at Respondent's business establishment, 4347 South Broadway, Saint Louis, Missouri 63111;
- On December 9, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-292, FDA Docket Number FDA-2013-H-1492, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24month period. CTP alleged those violations to have occurred on December 28, 2012, and May 20, 2013;
- The previous action concluded when the ALJ issued an Initial Decision and Default Judgment in which he found that Respondent Phillips 66 committed four violations of 21 C.F.R. pt. 1140. *S and B Fuel Inc. d/b/a Phillips 66, DAB CR3110, at 2-3 (2014)*; Complaint ¶ 11;
- At approximately 8:25 AM on June 10, 2014, at Respondent's business establishment, 4347 South Broadway, St. Louis, Missouri 63111, FDA-commissioned inspectors documented Respondent's staff selling a single Newport cigarette to a person younger than 18 years of age.

<sup>&</sup>lt;sup>1</sup> In the complaint, CTP describes the action or actions that took place at Respondent Phillips 66's business establishment on December 28, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint issued on December 9, 2013, attached to the present complaint, CTP described one discrete violation of 21 C.F.R. § 1140.14(d) at Respondent Phillips 66's business establishment on December 28, 2012. Therefore, I will infer that CTP's description in the present complaint of "violations" occurring on December 28, 2012, was a typographical error.

The inspectors also documented that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older.

These facts establish Respondent'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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Additionally, the regulations prohibit the sale of individual cigarettes. 21 C.F.R. § 1140.14(d).

## Order

Under 21 C.F.R. § 17.2, a \$10,000 civil money penalty is permissible for a total of six violations of the regulations found at 21 C.F.R. pt. 1140 within a period of 48 months. For these reasons, I enter default judgment in the amount of \$10,000 against S and B Fuel, Inc. 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.

/s/

Catherine Ravinski Administrative Law Judge