

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

PS Investments, LLC d/b/a Air Park BP

Respondent.

Docket No. C-12-1126

FDA Docket No. FDA-2012-H-0887

Decision No. CR2629

Date: September 28, 2012

**INITIAL DECISION AND DEFAULT JUDGMENT**

I enter a default judgment against Respondent, PS Investments, LLC d/b/a Air Park BP. The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority that are sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not timely answer the complaint, nor did Respondent request an extension of time within which to file an answer.

CTP began this case by serving a complaint on Respondent 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 impermissibly sold tobacco products to a minor and failed to verify the age of a person purchasing tobacco products, violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On August 21, 2012, CTP served the complaint on Respondent by United Parcel Service, as 21 C.F.R. §§ 17.5 and 17.7 provides. 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 Respondent to pay the full amount of the proposed penalty. Respondent did not file an answer within the time provided by regulation.

I am required to issue a default judgment if the complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the administrative complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the complaint are true. Specifically:

- Respondent owns a business that sells tobacco products under the name of Air Park BP. The business is located at 19230 Woodfield Road, Gaithersburg, Maryland 20879.
- On November 9, 2011, an FDA-commissioned inspector made observations at Respondent's place of business that included: the sale of cigarettes or smokeless tobacco to a minor under the age of 18; and failure to verify the identification of the purchaser by means of photo identification containing the bearer's date of birth.
- On January 12, 2012, CTP issued a Warning Letter to Respondent that recited the November 9, 2011 observations. The letter informed Respondent that the observed facts constituted violations of regulations at 21 CFR § 1140.14(a) and (b), which prohibited sales of tobacco products to individuals under the age of 18 and that required sellers of tobacco products to verify the age of purchasers by means of photo identification containing the bearer's date of birth. The letter advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.
- The Warning Letter was delivered to Respondent. On January 17, 2012, Mr. Chris Schwartz, who represented himself as Respondent's Manager, contacted CTP by telephone. Mr. Schwartz asserted that Respondent took the allegations of noncompliance very seriously and stated that Respondent

would reply in writing to those allegations. However, no written reply was received by CTP.

- On April 10, 2012, at about 11:21A.M. ET, an inspector observed a minor under the age of 18 buy a package of Newport Kings cigarettes at Respondent's place of business.

These facts establish that Respondent is liable 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. § 387c(a)(7)(B); 21 C.F.R. § 1140(b). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no person purchasing the tobacco product is younger than 18 years of age.

Here, Respondent sold tobacco products to individuals younger than age 18 on two occasions, on November 9, 2011, and on April 10, 2012. On November 9, 2011, Respondent failed to verify the age of the purchaser. These actions and omissions by Respondent constitute violations of law for which a civil money penalty is merited. Therefore, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2.

/s/

Steven T. Kessel  
Administrative Law Judge