Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Harvey Davis and Patricia Davis d/b/a Greenfield Trading Post,

Respondent.

Docket No. C-12-583 FDA Docket No. FDA-2012-H-0382

Decision No. CR2557

Date: June 20, 2012

DECISION AND ORDER OF DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving a complaint on Respondent, Harvey Davis and Patricia Davis, doing business as Greenfield Trading Post (Greenfield), at 325 North Grand Street, Greenfield, MO 65661. The complaint alleges that Greenfield sold tobacco products to a minor, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, 21 C.F.R. Part 1140, and seeks a \$250 civil money penalty.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on April 19, 2012, CTP served the complaint on Respondent Greenfield by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent Greenfield 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 Greenfield has not filed an answer within the time prescribed. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint are true. Specifically:

- On June 27, 2011, FDA-commissioned inspectors inspected the Greenfield establishment and observed the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age;
- In a warning letter dated September 22, 2011, the CTP informed Respondent Greenfield of the inspector's June 27, 2011 observations, and that such sales violate federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Greenfield's failure to correct its violation[s] could result in a civil money penalty or other regulatory action;
- On January 27, 2012, at 7:58 p.m. CST, an FDA-commissioned inspector documented that a person younger than 18 years of age was able to purchase a package of Red Seal Long Cut Wintergreen smokeless tobacco from Respondent Greenfield.

These facts establish Respondent Greenfield'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 as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 § 101, Pub. L. 111-31, (current version at 21 U.S.C. § 387f(d)). *See* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. §1140.1(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. A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250.00 against Respondent. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties within 30 days of the date of its issuance.

/s/

Carolyn Cozad Hughes Administrative Law Judge