

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1350)

Complainant,

v.

Kasco Enterprises, Inc. / Kathy Stockwell
d/b/a Spokane Handi Mart,

Respondent.

Docket No. C-14-1862

Decision No. CR3464

Date: November 17, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Kasco Enterprises, Inc. / Kathy Stockwell, d/b/a Spokane Handi Mart, at 153 Calabash Drive, Spokane, Missouri 65754, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Spokane Handi Mart unlawfully sold cigarettes to minors, 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 Spokane Handi Mart.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 16, 2014, CTP served the complaint on Respondent Spokane Handi Mart 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 Spokane Handi Mart 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 approximately 4:12 p.m. on July 10, 2013, at Respondent's business establishment, at 153 Calabash Drive, Spokane, Missouri 65754, an FDA-commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Wintergreen smokeless tobacco;
- In a warning letter dated October 31, 2013, CTP informed Respondent of the inspector's July 10, 2013 observation, and that such actions violate federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 10:31 a.m. on March 4, 2014, at Respondent's business establishment, at 153 Calabash Drive, Spokane, Missouri 65754, FDA-commissioned inspectors observed a person younger than 18 years of age was able to purchase a package of Pall Mall Red cigarettes.

These facts establish Respondent Spokane Handi Mart'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 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 against Respondent Kasco Enterprises, Inc. / Kathy Stockwell, d/b/a Spokane Handi Mart. 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