

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1149)

Complainant

v.

Barbara Reed d/b/a Cromwell General Store,

Respondent.

Docket No. C-14-1652

Decision No. CR3409

Date: October 8, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Barbara Reed d/b/a Cromwell General Store, at 101 South Shawnee Avenue, Cromwell, Oklahoma 74837,¹ and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Cromwell General Store unlawfully sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser 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,

¹ My office sent an Initial Order Establishing Procedures to the Respondent at this address indicating that it must respond to CTP's complaint within 30 days of service of the complaint or the Administrative Law Judge assigned to this case would decide this matter without a hearing. The United States Postal Service returned the mailing as undeliverable. However, CTP filed a proof of service of their complaint and cover letter which informed the Respondent that it must take action within 30 days after delivery of the complaint. Therefore, the Respondent had notice of the complaint and that it is subject to default.

21 C.F.R. pt. 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Cromwell General Store.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 11, 2014, CTP served the complaint on Respondent Cromwell General Store 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 Cromwell General Store 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 Respondent's business establishment, 101 South Shawnee Avenue, Cromwell, Oklahoma 74837, on September 5, 2013, at approximately 10:49 AM, an FDA-commissioned inspector observed Respondent's staff sell a package of Grizzly Fine Cut Premium Natural smokeless tobacco to a person younger than 18 years of age;
- In a warning letter issued on October 31, 2013, CTP informed Respondent of the inspector's observation from September 5, 2013, and that such an action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that if Respondent failed to correct its violation, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 101 South Shawnee Avenue, Cromwell, Oklahoma 74837, on February 15, 2014, at approximately 10:34 AM, FDA-commissioned inspectors documented Respondent's staff selling a package of Camel Blue cigarettes to a person younger than 18 years of age. 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 or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photo identification containing the bearer's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age.

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 Barbara Reed d/b/a Cromwell General Store. 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