

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2177)

Complainant,

v.

Reed's Grocery, Inc,

Respondent.

Docket No. C-15-657

Decision No. CR3720

Date: March 25, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Reed's Grocery, Inc., at Rural Route 1, Box 70, Cave In Rock, Illinois 62919, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Reed's Grocery, Inc. unlawfully sold tobacco products to a minor, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Reed's Grocery previously admitted to five violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$10,000 civil money penalty against Respondent Reed's Grocery, Inc.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 26, 2015, CTP served the complaint on Respondent Reed's Grocery, Inc. by United States Postal 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 Reed's Grocery, Inc. 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 Reed's Grocery, Inc. on December 1, 2011, citing violations of 21 C.F.R. pt. 1140 on September 28, 2011, at Respondent's business establishment, Rural Route 1, Box 70, Cave In Rock, Illinois 62919;
- On March 25, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-558, FDA Docket Number FDA-2013-H-0334, against Respondent for five violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred on September 28, 2011, April 2, 2012, and October 30, 2012;
- The previous action concluded when Rose Reed, Respondent's authorized representative, settled the claims on Respondent's behalf. On May 6, 2013, Ms. Reed signed an Acknowledgment Form in which she "admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on July 2, 2013;
- At approximately 1:50 p.m. on August 15, 2013, at Respondent's business establishment, Rural Route 1, Box 70, Cave In Rock, Illinois 62919, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes.

These facts establish Respondent Reed's Grocery, Inc.'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). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

