

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2261)

Complainant

v.

Bi-Lo, LLC
d/b/a Bi-Lo 5580,

Respondent.

Docket No. C-15-738

Decision No. CR3664

Date: February 24, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Bi-Lo, LLC d/b/a Bi-Lo 5580, at 2916 Emanuel Church Road, West Columbia, South Carolina 29170, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Bi-Lo 5580¹ impermissibly sold tobacco products 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 Bi-Lo 5580.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 30, 2014, CTP served the complaint on Respondent Bi-Lo 5580 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.

¹ The complaint states that Bi-Lo LLC has also done business under the name Bi-Lo 580.

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 Bi-Lo 5580 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 7:28 p.m. on October 29, 2013, at Respondent's business establishment, 2916 Emanuel Church Road, West Columbia, South Carolina 29170, an FDA-commissioned inspector observed Respondent's staff selling a package of Grizzly Long Cut Wintergreen smokeless tobacco to a person younger than 18 years of age;
- In a warning letter dated January 9, 2014, CTP informed Respondent of the inspector's October 29, 2013, observation, and that such action violates 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 12:30 p.m. on August 5, 2014, at Respondent's business establishment, 2916 Emanuel Church Road, West Columbia, South Carolina 29170, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent Bi-Lo 5580'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 tobacco products 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 Bi-Lo, LLC d/b/a Bi-Lo 5580. 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