

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1135)

Complainant

v.

Damen, Inc. d/b/a Damen Food and Liquor,

Respondent.

Docket No. C-14-1646

Decision No. CR3402

Date: October 3, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Damen, Inc. d/b/a Damen Food and Liquor, at 1956 West School Street, Chicago, Illinois 60657, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Damen Food and Liquor 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 Damen Food and Liquor.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 7, 2014, CTP served the complaint on Respondent Damen Food and Liquor 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 Damen Food and Liquor 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, 1956 West School Street, Chicago, Illinois 60657, on August 2, 2013, at approximately 1:11 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Marlboro cigarettes to a person younger than 18 years of age;
- In a warning letter issued on September 12, 2013, CTP informed Respondent of the inspector's observation from August 2, 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, 1956 West School Street, Chicago, Illinois 60657, on February 12, 2014, at approximately 4:44 PM, 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'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 cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

