

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2013-H-1585)

Complainant

v.

Smokes 4 Less #6 Inc.  
d/b/a Smokes 4 Less

Respondent.

Docket No. C-14-365

Decision No. CR3099

Date: February 10, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Smokes 4 Less #6 Inc. d/b/a Smokes 4 Less, at 1130 South Riverfront Drive, Mankato, Minnesota 56001 and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Smokes 4 Less impermissibly utilized self-service displays of tobacco products in a non-exempt facility, and distributed free samples of cigarettes violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose a \$250 civil money penalty against Respondent Smokes 4 Less.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 27, 2013, CTP served the complaint on Respondent Smokes 4 Less 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 Smokes 4 Less 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, 1130 South Riverfront Drive, Mankato, Minnesota 56001, on September 27, 2012, an FDA-commissioned inspector observed that Respondent had self-service displays of cigarette tobacco in customer-accessible parts of the establishment. The inspector also observed that Respondent did not prohibit individuals who were 18 years of age or younger from entering the establishment;
- In a warning letter dated December 6, 2012, CTP informed Respondent of the inspector's September 27, 2012 observation, and that such an action violates federal law. 21 C.F.R. § 1140.16(c). The letter further warned that if Respondent failed to correct its violation, a civil money penalty or other regulatory action could occur;
- During an inspection conducted on June 5, 2013, at Respondent's establishment, 1130 South Riverfront Drive, Mankato, Minnesota 56001, FDA-commissioned inspectors observed that Respondent offered free samples of a cigarette labeled as "Smokin Joes" in the forms of non-filter, white, and menthol 100's.

These facts establish Respondent Smokes 4 Less 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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). Under 21 C.F.R. § 1140.16(c), retailers are required to sell cigarettes or smokeless tobacco exclusively in face-to-face transactions and are prohibited from using self-service displays to sell cigarettes or smokeless tobacco, except where the establishment does not permit minors to enter or be present at any time. 21 C.F.R. § 1140.16(c)(2)(ii). The regulations further prohibit the distribution of any free samples of cigarettes, smokeless tobacco, or other tobacco products. 21 C.F.R. § 1140.16(d)(1).

