

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2013-H-0413)

Complainant

v.

JEC, Inc.
d/b/a Atkins Shell,

Respondent.

Docket No. C-13-633

Decision No. CR2800

Date: May 28, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, JEC, Inc. d/b/a Atkins Shell, at 1202 North Church Street, Atkins, Arkansas 72823, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Atkins Shell impermissibly sold cigarettes or smokeless tobacco to a minor, 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 \$500 civil money penalty against Respondent Atkins Shell.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on April 12, 2013, CTP served the complaint on Respondent Atkins Shell 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 Atkins Shell 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, 1202 North Church Street, Atkins, Arkansas 72823, on May 20, 2011, an FDA-commissioned inspector observed Respondent's staff sell cigarettes or smokeless tobacco to a person younger than 18 years of age;
- In a warning letter issued August 11, 2011, CTP informed Respondent of the inspector's May 20, 2011 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 violation could result in a civil money penalty or other regulatory action;
- On February 3 and 9, 2012, at Respondent's business establishment, 1202 North Church Street, Atkins, Arkansas 72823, inspectors documented that Respondent's staff again sold tobacco products to a person younger than 18 years of age;
- On June 6, 2012, CTP commenced a civil money penalty action against Respondent based on the preceding events. Respondent paid a \$250 penalty, and this tribunal closed the case;
- At approximately 10:36 a.m. on November 20, 2012, at Respondent's business establishment, 1202 North Church Street, Atkins, Arkansas 72823, an FDA-commissioned inspector observed Respondent's staff sell a package of Pall Mall Blue to a person younger than 18 years of age.

These facts establish Respondent Atkins Shell'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 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. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.

