

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1084)

Complainant

v.

Sahkar LLC / Dharmendrasinh Chudasama
d/b/a Centreville BP,

Respondent.

Docket No. C-14-1577

Decision No. CR3400

Date: October 2, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Sahkar LLC / Dharmendrasinh Chudasama d/b/a Centreville BP, at 7206 Centreville Road, Manassas, Virginia 20111, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Centreville BP impermissibly 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 Centreville BP.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 31, 2014, CTP served the complaint on Respondent Centreville BP 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 Centreville BP has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer.¹ 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 11:56 a.m. on April 28, 2013, at Respondent's business establishment, 7206 Centreville Road, Manassas, Virginia 20111, an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age;
- In a warning letter dated May 9, 2013, CTP informed Respondent of the inspector's April 28, 2013 observation, and that such actions violate 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;
- At approximately 3:51 p.m. on February 4, 2014, at Respondent's business establishment, 7206 Centreville Road, Manassas, Virginia 20111, FDA-commissioned inspectors documented Respondent's staff selling a package of Marlboro cigarettes to a person younger than 18 years of age.

These facts establish Respondent Centreville BP'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 cigarettes to any person younger than 18 years of age.

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

¹ On August 11, 2014, my office received a check from Respondent made out to "FDA." My office returned the check to the Respondent on August 14, 2014, with a letter explaining that all payments in civil money penalty actions must be sent directly to the Center for Tobacco Products.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Sahkar LLC / Dharmendrasinh Chudasama d/b/a Centreville BP. 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