

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1381)

Complainant,

v.

Sandys Stop and Shop LLC / Sandra Knapic
d/b/a Sandy's Stop N' Shop,

Respondent.

Docket No. C-14-1894

Decision No. CR3482

Date: November 24, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Sandys Stop and Shop LLC / Sandra Knapic d/b/a Sandy's Stop N' Shop, 1939 Highway 15 South, Saint George, South Carolina 29477, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Sandy's Stop N' Shop unlawfully sold cigarettes to minors and failed to verify that the cigarette purchasers were 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Sandy's Stop N' Shop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 23, 2014, CTP served the complaint on Respondent Sandy's Stop N' Shop 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 Sandy's Stop N' Shop 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 11:32 a.m. on September 14, 2013, at Respondent's business establishment, at 1939 Highway 15 South, Saint George, South Carolina 29477, an FDA-commissioned inspector observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100 cigarettes. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.
- In a warning letter dated November 7, 2013, CTP informed Respondent of the inspector's September 14, 2013 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). 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 9:29 a.m. on July 9, 2014, at Respondent's business establishment, at 1939 Highway 15 South, Saint George, South Carolina 29477, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes. The inspectors also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent Sandy's Stop N' Shop'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 to any person younger than 18 years of age.

21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

A \$500 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Sandys Stop and Shop LLC / Sandra Knapic d/b/a Sandy's Stop N' Shop. 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