

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1348)

Complainant

v.

Regent Trading Inc.
d/b/a Somers Point Lukoil,

Respondent.

Docket No. C-14-1860

Decision No. CR3516

Date: December 16, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Regent Trading Inc. d/b/a Somers Point Lukoil, at 324 New Road, Somers Point, New Jersey 08244, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Somers Point Lukoil impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the 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, 21 C.F.R. pt. 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Somers Point Lukoil.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 16, 2014, CTP served the complaint on Respondent Somers Point Lukoil 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. On October 16, 2014, Respondent Somers Point Lukoil, through counsel, filed a request for an extension of time to file an answer. CTP did not oppose Respondent's request and I granted the request, giving Respondent until November 24, 2014 to file its answer.

However, Respondent Somers Point Lukoil has failed to file an answer. Pursuant to 21 C.F.R. § 17.11, I thus assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- At approximately 11:15 a.m. on October 27, 2013, at Respondent's business establishment, 324 New Road, Somers Point, New Jersey 08244, an FDA-commissioned inspector observed Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age. The inspector also observed 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 January 9, 2014, CTP informed Respondent of the inspector's October 27, 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 11:09 a.m. on March 15, 2014, at Respondent's business establishment, 324 New Road, Somers Point, New Jersey 08224, FDA-commissioned inspectors documented Respondent's staff selling a package of Skoal Long Cut Classic Mint smokeless tobacco to a person younger than 18 years of age. 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 Somers Point Lukoil'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 a tobacco product to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age.

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

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Regent Trading Inc. d/b/a Somers Point Lukoil. 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