

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1013)

Complainant,

v.

Cob Investment Management, LLC / Linda Hansen
d/b/a Lu's Smoke Shop,

Respondent.

Docket No. C-14-1503

Decision No. CR3423

Date: October 17, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Cob Investment Management, LLC / Linda Hansen d/b/a Lu's Smoke Shop, at 1227 North Goerig Street, Suite C, Woodland, Washington 98674 and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Lu's Smoke Shop unlawfully sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that a cigarette purchaser was 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 \$250 civil money penalty against Respondent Lu's Smoke Shop.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on August 19, 2014, CTP served the complaint on Respondent Lu's Smoke 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 Lu's Smoke 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 Respondent's business establishment, 1227 North Goerig Street, Suite C, Woodland, Washington 98674, on November 25, 2013, at approximately 4:03 PM, an FDA-commissioned inspector observed Respondent's staff sell a package of Camel Blue 99's cigarettes to a person younger than 18 years of age. The inspector also observed that Respondent's staff failed to verify, by means of photo identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older;
- In a warning letter issued on February 6, 2014, CTP informed Respondent of the inspector's observations from November 25, 2013, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that if Respondent failed to correct its violations, the FDA could impose a civil money penalty or take other regulatory action;
- At Respondent's business establishment, 1227 North Goerig Street, Suite C, Woodland, Washington 98674, on April 23, 2014, at approximately 2:16 PM, 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'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 or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photo identification containing the bearer's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age.

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

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Cob Investment Management, LLC / Linda Hansen d/b/a Lu's Smoke 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