Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2014-H-0915)

Complainant

v.

Alan A. Oraham d/b/a Smokes For Less,

Respondent

Docket No. C-14-1410

Decision No. CR3360

Date: September 8, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Alan A. Oraham d/b/a Smokes for Less, at 3046 West Devon Avenue, Chicago, Illinois 60659, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Smokes for Less: impermissibly sold cigarettes to minors; failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older; and, utilized a self-service display of tobacco products, 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 \$2,000 civil money penalty against Respondent Smokes for Less.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 8, 2014, CTP served the complaint on Respondent Smokes for Less 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 Smokes for Less 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 11:20 a.m. on August 9, 2013, at Respondent's business establishment, 3046 West Devon Avenue, Chicago, Illinois 60659, an FDA-commissioned inspector observed Respondent's staff selling a package of Kite Mentholated cigarette tobacco 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 issued September 26, 2013, CTP informed Respondent of the inspector's August 9, 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 5:08 p.m. on January 15, 2014, at Respondent's business establishment, 3046 West Devon Avenue, Chicago, Illinois 60659, FDA-commissioned inspectors documented Respondent's staff selling a package of TOP Menthol Premium cigarette 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. Lastly, the inspectors documented the presence of a wall display containing cigarette tobacco on the main sales floor.

These facts establish Respondent Smokes for Less' 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. 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 cigarette purchasers are younger than 18 years of age. Finally, under 21 C.F.R. § 1140.16(c), self-service displays of cigarettes and smokeless tobacco are prohibited as a means of sale, except in facilities in which no minor is allowed to enter the facility at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

A \$2,000 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Alan A. Oraham d/b/a Smokes for Less. 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