Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2013-H-0158)

Complainant

v.

Yong Sheng Liu d/b/a Hao Sam Chinese Restaurant,

Respondent.

Docket No. C-13-404

Decision No. CR2738

Date: March 28, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Yong Sheng Liu d/b/a Hao Sam Chinese Restaurant, at 3901 North Broad Street, Philadelphia, PA 19140, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Hao Sam Chinese Restaurant impermissibly sold cigarettes or smokeless tobacco to a minor and failed to verify the purchaser's age by means of photo identification containing a date of birth, violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose a \$500 civil money penalty against Respondent Hao Sam Chinese Restaurant.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on February 14, 2013, CTP served the complaint on Respondent Hao Sam Chinese Restaurant 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 Hao Sam Chinese Restaurant 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, 3901 North Broad Street, Philadelphia, PA 19140, on August 11, 2011, an FDA-commissioned inspector observed a sale of cigarettes or smokeless tobacco to a person younger than 18 years of age;
- At Respondent's business establishment, 3901 North Broad Street, Philadelphia, PA 19140, on August 11, 2011, an FDA-commissioned inspector observed that staff failed to verify, by means of photo identification containing the bearer's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age;
- In a warning letter dated November 10, 2011, CTP informed Respondent of the inspector's August 11, 2011 observations, and that such actions violate federal law, 21 C.F.R. §§ 1140.14(a) and 1140.14(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 5:05 p.m. on April 18, 2012, at Respondent's business establishment, 3901 North Broad Street, Philadelphia, PA 19140, an FDA commissioned inspector observed the sale of a package of Newport Box 100s cigarettes to a person younger than 18 years of age; staff also failed to verify, by means of photo identification containing the bearer's date of birth, the purchaser's age.

These facts establish Respondent Hao Sam Chinese Restaurant'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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); see 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 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), a retailer must verify, by means of

photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age.

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 Yong Sheng Liu d/b/a Hao Sam Chinese Restaurant. Pursuant to 21 C.F.R. § 17.11 (b), this order becomes final and binding upon both parties within 30 days of the date of its issuance.

/s/ Carolyn Cozad Hughes Administrative Law Judge