Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

V.

Rui Xin Liu d/b/a Sing Gong Restaurant,

Respondent.

Docket No. C-14-988 FDA Docket No. FDA-2014-H-0499

Decision No. CR3280

Date: June 30, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Rui Xin Liu d/b/a Sing Gong Restaurant, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500. Respondent did not timely answer the Complaint, nor did Respondent request an extension of time within which to file an Answer. Therefore, I enter a default judgment against Respondent and order that Respondent pay a civil money penalty in the amount of \$500.

CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff unlawfully sold cigarettes to minors, and failed to verify the age of the purchasers, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$500.

On May 6, 2014, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. 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 within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Sing Gong Restaurant, an establishment that sells tobacco products and is located at 5900 Belmar Terrace, Philadelphia, Pennsylvania 19143. Complaint ¶ 3.
- During a May 30, 2013 inspection of Respondent's establishment, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Menthol Gold Box 100s cigarettes . . . at approximately 7:35 PM[.]" The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- on June 20, 2013, CTP issued a Warning Letter to Sing Gong Restaurant regarding the inspector's observations from May 30, 2013. The letter explained that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter also stated that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- On August 20, 2013, Rui Xin Liu, owner of Sing Gong Restaurant, responded to the Warning Letter on his own behalf in a letter. "Mr. Liu stated that [he would] let employees know to only sell cigarettes and smokeless tobacco to anyone age 18 or older and to check the photo ID

with date of birth of anyone under age 27 who attempts to purchase cigarettes or smokeless tobacco." Complaint ¶ 11.

• On December 18, 2013, during a subsequent inspection of Respondent's establishment, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Newport cigarettes . . . at approximately 5:16 PM[.]" The inspectors also observed that "the minor's identification was not verified before the sale" Complaint ¶ 1.

These facts establish that Respondent is liable 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. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). The Secretary issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). Under 21 C.F.R. § 1140.14(a), a retailer is prohibited from selling 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 cigarette or smokeless tobacco purchasers are younger than 18 years of age.

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to a person younger than 18 years of age on May 30, 2013, and December 18, 2013. Respondent also violated 21 C.F.R. § 1140.14(b)(1) on May 30, 2013, and December 18, 2013, when its staff failed to verify, by checking the minor's photographic identification, that a tobacco purchaser was 18 years of age or older. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$500, which is a permissible civil money penalty under the regulations. 21 C.F.R. § 17.2. Accordingly, I order Respondent to pay a civil money penalty in the amount of \$500.

/s/

Steven T. Kessel Administrative Law Judge