

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-0220)

Complainant,

v.

Zu Rong Zou
d/b/a Grace Garden,

Respondent.

Docket No. C-15-1031

Decision No. CR3730

Date: March 27, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Zu Rong Zou d/b/a Grace Garden, at 5025 Germantown Avenue, Philadelphia, Pennsylvania 19144, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Grace Garden unlawfully sold tobacco products to minors and failed to verify that a 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Grace Garden previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$2,000 civil money penalty against Respondent Grace Garden.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 28, 2015, CTP served the complaint on Respondent Grace Garden 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 Grace Garden 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:

- CTP previously issued a warning letter to Respondent Grace Garden on September 15, 2011, citing violations of 21 C.F.R. pt. 1140 on June 6, 2011, at Respondent's business establishment, 5025 Germantown Avenue, Philadelphia, Pennsylvania 19144;
- On July 5, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-955, FDA Docket Number FDA-2013-H-1452, against Respondent for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged two of those violations to have occurred on December 31, 2012;
- The previous action concluded when Zu Rong Zou, Respondent's authorized representative, settled the claims on Respondent's behalf. On September 16, 2013, Mr. Zou signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on October 18, 2013;
- At approximately 1:43 p.m. on August 11, 2014, at Respondent's business establishment, 5025 Germantown Avenue, Philadelphia, Pennsylvania 19144, FDA-commissioned inspectors observed that a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes. The inspector 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 Grace Garden'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).

The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

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 Zu Rong Zou d/b/a Grace Garden. 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