

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1480)

Complainant

v.

Chaesun Han Osaka
d/b/a North Park Grocery,

Respondent.

Docket No. C-15-1

Decision No. CR3496

Date: December 4, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Chaesun Han Osaka, d/b/a North Park Grocery, at 10332 Aurora Avenue North, Seattle, Washington 98133, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that North Park Grocery impermissibly used a self-service display in a non-exempt location, 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. The Complaint likewise alleges that Respondent North Park Grocery previously admitted to two violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$500 civil money penalty against Respondent North Park Grocery.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on October 8, 2014, CTP served the complaint on Respondent North Park Grocery 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 North Park Grocery 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 North Park Grocery on January 3, 2013, citing violations of 21 C.F.R. pt. 1140 on December 15, 2012, at Respondent's business establishment, 10332 Aurora Avenue North, Seattle, Washington 98133;
- On September 18, 2013, CTP initiated a civil money penalty action, CRD Docket Number C-13-1133, FDA Docket Number FDA-2013-H-0934, against Respondent North Park Grocery for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on December 15, 2012, and May 8, 2013;
- The previous action concluded when Chaesun Osaka, Respondent's authorized representative, settled the claims on Respondent's behalf. On January 31, 2014, Ms. Osaka signed an Acknowledgment Form in which she "admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that the 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 February 18, 2014;
- During a two-part inspection at Respondent's business establishment, 10332 Aurora Avenue North, Seattle, Washington 98133, conducted on March 22 and 25, 2014, FDA-commissioned inspectors documented the presence of a self-service display of cigarette tobacco.

These facts establish North Park Grocery'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 require a retailer to sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange.
21 C.F.R. § 1140.16(c).

Under 21 C.F.R. § 17.2, a \$500 civil money penalty is permissible for three violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$500 against Respondent Chaesun Han Osaka, d/b/a North Park Grocery. 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