

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Jennifer Joung-Ok Lee and Si-Won Lee
d/b/a Corner Store,

Respondent.

Docket No. C-15-378
FDA Docket No. FDA-2014-H-1912

Decision No. CR3575

Date: January 15, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Jennifer Joung-Ok Lee and Si-Won Lee d/b/a Corner Store that alleges facts and legal authority sufficient to justify the imposition of a \$500 civil money penalty. Respondent did not 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 assess a \$500 civil money penalty.

CTP began this case by serving the 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 utilized self-service displays in a non-exempt facility, sold cigarettes to a minor, and failed to verify by means of photo identification containing a date of birth, that a tobacco 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 (2013). CTP seeks a civil money penalty of \$500.

On November 19, 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 proposed 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Corner Store, an establishment that sells tobacco products and is located at 2809 Thorndyke Avenue West, Suite B, Seattle, Washington 98199. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on January 3, 2014, at an unspecified time, an FDA-commissioned inspector “observed smokeless tobacco for sale from multiple customer-accessible displays on the checkout counter.” The inspector also observed that “[t]he establishment was open to the general public during business hours.” Complaint ¶ 10.
- On February 27, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 3, 2014. The letter explained that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, 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.
- Although United Parcel Service records indicate that an individual named “Keum” received the letter, CTP did not receive a response. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment, conducted on May 16, 2014, at approximately 3:57 PM, FDA-commissioned inspectors documented

