

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Keun Hee Lee
d/b/a Sun Market,

Respondent.

Docket No. C-13-171
FDA Docket No. FDA-2012-H-1194

Decision No. CR2693

Date: January 22, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority sufficient to justify the imposition of a \$250 civil money penalty. 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, Keun Hee Lee d/b/a Sun Market, and assess a civil money penalty of \$250.

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 impermissibly sold tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser through photographic identification on one occasion, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing

regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250 for these three violations.

On December 14, 2012, 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, the Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such 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 that:

- Respondent owns Sun Market, an establishment that sells tobacco products and is located at 11101 West Buckeye Road, Cashion, Arizona 85329.
- On January 4, 2012, an FDA-commissioned inspector performed an inspection of Sun Market and noted two violations. First, the inspector observed the “[s]ale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a)[.]” Complaint ¶ 9.a. The inspector also observed the “[f]ailure to verify by means of photographic identification, containing the bearer’s date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age, as required by 21 C.F.R. § 1140.14(b)(1).” Complaint ¶ 9.b.
- CTP then issued a warning letter to Sun Market on March 1, 2012, informing Respondent of the violations that the FDA-commissioned inspector had observed on January 4, 2012. The letter advised that it was not intended to provide an exhaustive list of violations and that the failure to correct violations could result in the imposition of a civil money penalty or other regulatory action. Moreover, the letter informed that Sun Market maintained the responsibility to ensure that it complied with the law.
- On March 11, 2012, Respondent replied to CTP’s warning letter in writing and through representatives. Respondent “apologized for the sale and

stated the establishment would check identification with the sale of every tobacco product.” Complaint ¶ 10.

- Pursuant to a two-part inspection performed on May 31, and June 8, 2012, FDA-commissioned inspectors noted that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on May 31, 2012, at approximately 12:16 PM[,]” in violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 1.

Taking these facts as true, I must find pursuant to 21 C.F.R. § 17.11(a) 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require a retailer to “verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the product is younger than 18 years of age[,]” 21 C.F.R. § 1140.14(b)(1), though “[n]o such verification is required for any person over the age of 26[,]” 21 C.F.R. § 1140.14(b)(2).

Here, Respondent sold tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser on one of those occasions in violation of the foregoing regulations. Respondent’s actions and omission constitute violations of law for which a civil money penalty is merited. The regulations require the imposition of a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). Respondent has committed three violations within a 24-month period, the maximum penalty for which is \$500. 21 C.F.R. § 17.2; *Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (Revised)*, November 2012, (available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>). CTP, however, has requested a civil money penalty in the amount of \$250, which is the maximum penalty for the second violation committed within a 12-month period. Therefore, I impose a civil money penalty in the amount of \$250.

/s/
Steven T. Kessel
Administrative Law Judge