

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

James Kenneth Lee
d/b/a The Billiard Center,

Respondent.

Docket No. C-12-1085
FDA Docket No. FDA-2012-H-0843

Decision No. CR2621

Date: September 21, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

I enter a default judgment against Respondent, James Kenneth Lee d/b/a The Billiard Center. The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority that are sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not timely answer the complaint, nor did Respondent request an extension of time within which to file an answer.

CTP began this case by serving a complaint on Respondent and by 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 and failed to verify the age of a person purchasing tobacco products, violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000.

On August 13, 2012, CTP served the complaint on Respondent by United Parcel Service, as is 21 C.F.R. §§ 17.5 and 17.7 provide. 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 did not file an answer within the time provided by regulation.

I am required to issue a default judgment if the complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the administrative complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the complaint are true. Specifically:

- Respondent owns a business that sells tobacco products under the name of The Billiard Center, located at 26 North Main Street, Cape Girardeau, Missouri 63701.
- On August 29, 2011, an FDA-commissioned inspector made observations at Respondent's place of business that included: failure to sell cigarettes or smokeless tobacco in a direct, face-to-face exchange without the assistance of any electronic or mechanical device in a facility that does not ensure that no person younger than 18 years of age is present or permitted to enter, at any time, as 21 C.F.R. § 1140.14(c) requires; and failure to ensure that all violative items in Respondent's establishment were removed or brought into compliance with the requirements of 21 C.F.R. Part 1140, as 21 C.F.R. § 1140.14(e) requires.
- On November 10, 2011, CTP issued a Warning Letter to Respondent. The letter informed Respondent of the violations that were observed on August 29, 2011, and it advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.
- The Warning Letter was delivered to Respondent. Respondent did not reply to the Warning Letter.

