

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Keyes Canoe Rental Inc.
d/b/a Ozark Outdoors Riverfront Resort,

Respondent.

Docket No. C-15-881
FDA Docket No. FDA-2015-H-0080

Decision No. CR3683

Date: March 4, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Keyes Canoe Rental Inc. d/b/a Ozark Outdoors Riverfront Resort, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500. 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 and order that Respondent pay a civil money penalty in the amount of \$500.

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's staff unlawfully sold cigarettes to a minor, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$500.

On January 13, 2015, 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 an Administrative Law Judge could issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Ozark Outdoors Riverfront Resort, an establishment that sells tobacco products and is located at 200 Ozark Outdoor Lane, Leasburg, Missouri 65535. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-689, FDA Docket Number FDA-2014-H-0187, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, on April 21, 2013 and September 23, 2013, Respondent sold tobacco products to a minor and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older. Complaint ¶ 10.
- The previous civil money penalty action concluded when Tera Reed, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. On April 6, 2014, Ms. Reed signed an Acknowledgment Form in which she "admitt[ed] that the violations . . . occurred, waiv[ed] Respondent's ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions against Respondent." The Administrative Law Judge closed the case on April 16, 2014. Complaint ¶ 11.
- During a subsequent two-part inspection of Respondent's establishment conducted on July 14 and 18, 2014, FDA-commissioned inspectors documented that a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on July 14, 2014 at approximately 8:46 AM. Complaint ¶ 1.

