

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Shane F. Baker  
d/b/a Average Joe's,

Respondent.

Docket No. C-15-909  
FDA Docket No. FDA-2015-H-0108

Decision No. CR3706

Date: March 11, 2015

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Shane F. Baker d/b/a Average Joe's that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 civil money penalty of \$250.

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 impermissibly sold cigarettes to minors, 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 \$250.

On January 16, 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 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 Average Joe’s, an establishment that sells tobacco products and is located at 311 North Highway 39, Miller, Missouri 65707. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on December 31, 2013, at approximately 2:08 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Pall Mall Red cigarettes . . . [.]” Complaint ¶ 10.
- On March 27, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from December 31, 2013. The letter explained that the observations constituted violation of the regulation found at 21 C.F.R. § 1140.14(a), 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 “GH” received the Warning Letter on March 28, 2014, the FDA did not receive a response. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on June 5, 2014, at approximately 1:51 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Pall Mall Red cigarettes . . . [.]” Complaint ¶ 1.

These facts establish 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

