

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Gary Schramer  
d/b/a Twin Liquors,

Respondent.

Docket No. C-14-1290  
FDA Docket No. FDA-2014-H-0783

Decision No. CR3321

Date: August 7, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Gary Schramer d/b/a Twin Liquors, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$250. 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 \$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's staff unlawfully sold cigarettes to minors and failed to verify that a cigarette purchaser was of sufficient age, 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 \$250.

On June 18, 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 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 by default 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. 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 Twin Liquors, an establishment that sells tobacco products and is located at 975 North Farnsworth Avenue, Aurora, Illinois 60505. Complaint ¶ 3.
- During an inspection of the establishment conducted on July 26, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 1:43 PM [.]” The inspector also observed that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 10.
- On September 5, 2013, CTP issued a Warning Letter to Twin Liquors explaining that the inspector’s July 26, 2013 observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1). In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violations. The letter also stated that it was Respondent’s responsibility to comply with the law. Complaint ¶ 10.
- The FDA did not receive a response to the Warning Letter, but delivery records show that an individual named “Gary” received it on September 6, 2013. Complaint ¶ 11.

