

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Malik B Inc.  
d/b/a Sam's Food Store,

Respondent.

Docket No. C-13-769  
FDA Docket No. FDA-2013-H-0566

Decision No. CR2897

Date: August 20, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, Malik B Inc. d/b/a Sam's Food Store, 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 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's staff unlawfully sold regulated tobacco products to minors and failed to verify that the tobacco purchasers were of sufficient age prior to these transactions, 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 \$500.

On June 28, 2013, CTP served the Complaint on Respondent by personal 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 did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default 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 must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

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 Sam's Food Store, an establishment that sells tobacco products and is located at 63 York Street, New Haven, Connecticut 06511.
- On July 25, 2012, an FDA-commissioned inspector observed violations of 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff "[sold] tobacco products to a minor." Respondent's staff also failed to "verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1)."
- On October 4, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from July 25, 2012. 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 Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law.
- The FDA did not receive a response to the Warning Letter, but United Parcel Service records show that "SHAPIK" received the letter on October 5, 2012.

