

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Babe Mart, LLC
d/b/a Babe's Market,

Respondent.

Docket No. C-13-717
FDA Docket No. FDA-2013-H-0512

Decision No. CR2835

Date: June 19, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Babe Mart, LLC d/b/a Babe's Market, alleging facts and legal authority sufficient to justify the imposition of 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 regulated tobacco products to minors and, prior to these transactions, failed to verify that the tobacco purchasers were of sufficient age, 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 May 6, 2013, 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 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 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 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 Babe's Market, an establishment that sells tobacco products and is located at 604 Ferry Street, New Haven, Connecticut 06513.
- On June 26, 2012, an FDA-commissioned inspector observed two violations of regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff sold tobacco products to a minor. During this same transaction, Respondent's staff failed to verify, by means of photographic identification containing the bearer's date of birth, the age of the tobacco purchaser as required by 21 C.F.R. § 1140.14(b)(1).
- On September 27, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from June 26, 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.

