

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Rafael Ramirez
d/b/a Tete Supermarket,

Respondent.

Docket No. C-14-857
FDA Docket No. FDA-2014-H-0375

Decision No. CR3234

Date: May 20, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Rafael Ramirez d/b/a Tete Supermarket, alleging facts and legal authority sufficient to justify the imposition of 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 assess a civil money penalty of \$250.

CTP initiated 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 a regulated tobacco product to a person younger than 18 years of age on two occasions, 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 \$250.

On April 4, 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 must take one of the following three actions: pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP further explained that if Respondent did not comply with one of the actions within 30 days, an Administrative Law Judge could issue an initial decision 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 Tete Supermarket, an establishment that sells tobacco products and is located at 3468 E Street, Philadelphia, Pennsylvania 19134. Complaint ¶ 3.
- During a June 5, 2013 inspection of Respondent's establishment, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . at approximately 4:23 PM." Complaint ¶ 10.
- On June 27, 2013, CTP issued a Warning Letter to Tete Supermarket regarding the inspector's observation from June 5, 2013. The letter explained that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter also stated 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.
- United Parcel Service records indicate that an individual named "Ramirez" received the Warning Letter on June 28, 2013, however, the FDA did not receive a response to the warning letter. Complaint ¶ 11.
- On October 27, 2013, during another inspection of Respondent's establishment, FDA-commissioned inspectors documented that "a person

