

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Quik Stop Auto Service, Inc.,

Respondent.

Docket No. C-13-392
FDA Docket No. FDA-2013-H-0141

Decision No. CR2733

Date: March 27, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Quik Stop Auto Service, Inc., 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 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 impermissibly sold tobacco products to a minor, 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 February 12, 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, the 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 one 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 Quik Stop Auto Service, Inc., a business that sells tobacco products and is located at 23418 Ridge Road, Germantown, Maryland 20876.
- On April 12, 2012, during an inspection of Respondent's establishment, an FDA-commissioned inspector observed a violation when Respondent sold cigarettes to a person younger than 18 years of age.
- On June 7, 2012, CTP issued a Warning Letter to Quik Stop Auto Service regarding the inspector's observations from April 12, 2012. The letter stated that Respondent's sale of tobacco products to a minor violated regulations found at 21 C.F.R. § 1140.14(a). The letter also advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.
- Delivery records show that an individual named "Bailey" received the Warning Letter on June 8, 2012. CTP did not receive a response to the Warning Letter.
- On October 18, 2012, FDA commissioned inspectors documented an additional violation during a subsequent inspection of the establishment. At approximately 2:13 P.M., a person younger than the age of 18 was able to purchase a package of "Newport Box" cigarettes.

