

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Goose Creek Market N Pub LLC,

Respondent.

Docket No. C-14-841
FDA Docket No. FDA-2014-H-0368

Decision No. CR3237

Date: May 20, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Goose Creek Market N Pub LLC, 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 smokeless tobacco to minors on two separate 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 2, 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 Goose Creek Market N Pub, an establishment that sells tobacco products and is located at 6161 Office Road, French Village, Missouri 63036. Complaint ¶ 3.
- On June 6, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco . . . at approximately 10:53 AM.” Complaint ¶ 10.
- On June 27, 2013, CTP issued a Warning Letter to Goose Creek Market N Pub explaining that the inspector’s June 6, 2013 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a). In addition to describing the violation, 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 violation. 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 United Parcel Service records show that an individual named “Friend” received it on June 28, 2013. Complaint ¶ 11.
- On November 2, 2013, during a subsequent inspection of Respondent’s establishment, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Grizzly

