

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Quest of Olanta, Inc.
d/b/a HD's Quick Stop,

Respondent.

Docket No. C-15-521
FDA Docket No. FDA-2014-H-2043

Decision No. CR3561

Date: January 9, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Quest of Olanta, Inc. d/b/a HD's Quick Stop, that alleges facts and legal authority sufficient to justify the imposition of a \$500 civil money penalty. Respondent did not 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 \$500 civil money penalty.

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 impermissibly sold tobacco products to minors and failed to verify that a tobacco purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140 (2013). CTP seeks a civil money penalty of \$500.

On December 3, 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 proposed 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 has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns HD’s Quick Stop, an establishment that sells tobacco products and is located at 519 East Hampton Street, Olanta, South Carolina 29114. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on December 3, 2013, at approximately 5:36 PM, 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” Complaint ¶ 10.
- On February 20, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from December 3, 2013. The letter explained that the observation constituted a violation of regulations found at 21 C.F.R. § 1140.14(a), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state 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.
- Although UPS records indicate that an individual named “Frye” received the Warning Letter, CTP did not receive a response to the Warning Letter. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on June 24, 2014, at approximately 5:12 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 1.

