

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

The Smoke House LLC,

Respondent.

Docket No. C-14-1276
FDA Docket No. FDA-2014-H-0774

Decision No. CR3326

Date: August 12, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, The Smoke House LLC, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 civil money penalty of \$250.

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 cigarettes to a minor, failed to verify that a cigarette purchaser was 18 years of age or older, and impermissibly utilized a self-service display of smokeless tobacco, 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 \$250.

On June 19, 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 The Smoke House, an establishment that sells tobacco products and is located at 6301 Rainier Avenue South, Suite 1, Seattle, Washington 98118. Complaint ¶ 2.
- During an inspection of Respondent’s establishment on February 24, 2013, at approximately 1:35 PM PT, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 9.
- On March 14, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 24, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 9.
- Saif Shmed, Respondent’s owner, responded to the Warning Letter in an April 3, 2013 letter. “Mr. Shmed stated that Respondent took disciplinary action against the employee who sold the tobacco product to the minor, that all employees will request identification from every tobacco purchaser, and that Mr. Shmed will

