

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Ishtar Greek Cuisine L.L.C.
d/b/a Ishtar Smoke Shop,

Respondent.

Docket No. C-15-446
FDA Docket No. FDA-2014-H-1977

Decision No. CR3555

Date: January 6, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Ishtar Greek Cuisine L.L.C. d/b/a Ishtar Smoke Shop that alleges facts and legal authority sufficient to justify the imposition of a \$250 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 \$250 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 cigarettes to minors, 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 November 26, 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 Ishtar Smoke Shop, an establishment that sells tobacco products and is located at 415 Central Avenue South, Kent, Washington 98032. Complaint ¶ 3.
- During an inspection of Respondent’s establishment on December 16, 2013, at approximately 7:14 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes” Complaint ¶ 10.
- On March 13, 2014, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from December 16, 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.
- David P. Richards, who identified himself as the bookkeeper for Ishtar Smoke Shop, responded to the Warning Letter by email. Mr. Richards stated that “Respondent took disciplinary action against the employee who sold tobacco product[s] to the minor. Mr. Richards also stated that the establishment changed its ‘policy to perform 100% ID checks on all tobacco sales’ and now randomly reviews surveillance footage to check compliance.” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on June 3, 2014, at approximately 2:57 PM, FDA-commissioned inspectors documented that “a

