

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Clark's Empire Food's Enterprise, Inc. / Heon Jo,
d/b/a Clark's Empire Foods,

Respondent.

Docket No. C-15-188
FDA Docket No. FDA-2014-H-1711

Decision No. CR3538

Date: December 30, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Clark's Empire Food's Enterprise, Inc. / Heon Jo d/b/a Clark's Empire Foods 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 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 October 30, 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 Clark's Empire Foods, an establishment that sells tobacco products and is located at 3361 Mapleway Road, Yakima, Washington 98908. Complaint ¶ 3.
- During an inspection of Respondent's establishment on November 24, 2013, at approximately 12:34 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes.” Complaint ¶ 10.
- On February 6, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from November 24, 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 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 ¶ 10.
- Although FDA did not receive a response to the Warning Letter, United Parcel Service records indicate the Warning Letter was received on February 7, 2014 by “Smith.” Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment on April 21, 2014, at approximately 2125 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes ... [.]” Complaint ¶ a.

