

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

China Royal LLC / Juan Chen Zhu,

Respondent.

Docket No. C-14-1884  
FDA Docket No. FDA-2014-H-1371

Decision No. CR3450

Date: November 10, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, China Royal LLC / Juan Chen Zhu, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$2,000. 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 \$2,000.

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 tobacco products to minors, failed to verify, by means of photo identification containing a date of birth, that tobacco purchasers were 18 years of age or older, and sold individual cigarettes on two occasions, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$2,000.

On September 17, 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

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 China Royal LLC / Juan Chen Zhu, an establishment that sells tobacco products and is located at 713 Frelinghuysen Avenue, Newark, New Jersey 07114. Complaint ¶ 3.
- During an inspection of Respondent's establishment on September 22, 2013, at approximately 1:52 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase one individual Newport cigarette . . . [.]". The inspector also observed that "the minor's identification was not verified before the sale . . . ." Complaint ¶ 10.
- On January 16, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observations from September 22, 2013. The letter explained that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.14(a), (b)(1), and (d), 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 ¶ 10.
- Although United Parcel Service records indicate that an individual named "Yia" received the warning letter, FDA never received a response. Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on April 5, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase two individual cigarettes . . . at

approximately 11:40 AM[.]” The inspectors also documented that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from “break[ing] or otherwise open[ing] any cigarette or smokeless tobacco package to sell or distribute individual cigarettes . . . .” 21 C.F.R. § 1140.14(d).

Taking the above alleged facts as true, Respondent had six violations of regulations contained in 21 C.F.R. Part 1140 within a twenty-four month period. Specifically, Respondent had three violations on September 22, 2013, and three violations on April 5, 2014. Respondent’s actions violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent’s actions also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, Respondent’s actions violated the prohibition against selling individual cigarettes. 21 C.F.R. § 1140.14(d). Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

CTP has requested a fine of \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

\_\_\_\_\_  
/s/  
Steven T. Kessel  
Administrative Law Judge