

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Radivoje Tupanjac  
d/b/a Dundee 53 Shell,

Respondent.

Docket No. C-14-508  
FDA Docket No. FDA-2014-H-0039

Decision No. CR3165

Date: March 19, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Radivoje Tupanjac d/b/a Dundee 53 Shell (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$250 civil money penalty. 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 assess a civil money penalty of \$250.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that on two occasions, Respondent's staff impermissibly sold cigarettes to a person younger than 18 years of age, thereby violating the Federal Food, Drug,

and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301 – 399d, and its implementing regulations, found at 21 C.F.R. Part 1140.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on January 28, 2014, via United Parcel Service. The Complaint and accompanying cover letter stated that within 30 days, Respondent must take one of the following three actions: pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP further explained that if Respondent did not comply with one of the actions within 30 days, an Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has neither filed an Answer within the time provided by regulation, nor timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act],” issue an initial decision and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Dundee 53 Shell, an establishment that sells tobacco products and is located at 1393 East Dundee Road, Palatine, Illinois 60074. Complaint ¶ 3.
- On February 18, 2013, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on February 18, 2013, at approximately 12:09 PM CT.” Complaint ¶ 10.
- On May 30, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from February 18, 2013. The letter explained that the observation constituted a violation of a regulation 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 also stated 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.
- On June 4, 2013, Robert Tupanjac, Respondent’s Owner, responded in writing to the Warning Letter on Respondent’s behalf. “Mr. Tupanjac stated that he took disciplinary action against the employee who sold the

tobacco product to [a] minor, and that he reminded all employees to verify the identification of all tobacco purchasers who do not appear to be over 40 years of age, including regular purchasers. Mr. Tupanjac also stated [that] he posted signage . . . stating that the establishment does not sell tobacco products to purchasers under 18 years of age.” Complaint ¶ 11.

- During a subsequent inspection of Respondent’s establishment conducted on September 17, 2013, FDA-commissioned inspectors documented an additional violation of the regulations found at 21 C.F.R. Part 1140. Specifically, “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on September 17, 2013, at approximately 2:53 PM.” Complaint ¶ 1.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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, codified at 21 U.S.C. § 387f(d). *See* 21 U.S.C. § 387(a)(7)(B); 21 C.F.R. § 1140.1(b). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

In the present case, on February 18, 2013, and September 17, 2013, Respondent’s staff sold cigarettes to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). Therefore, Respondent’s actions and omissions on multiple occasions constitute violations of law that merit a civil money penalty. Accordingly, I find that a civil money penalty in the amount of \$250 is permissible and order it imposed. 21 C.F.R. § 17.2.

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/s/  
Steven T. Kessel  
Administrative Law Judge