

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

K and S Market, LLC and Karwan Sofi,

Respondents.

Docket No. C-14-1898  
FDA Docket No. FDA-2014-H-1385

Decision No. CR3474

Date: November 21, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondents, K and S Market, LLC and Karwan Sofi that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. The Respondents did not answer the Complaint, nor did Respondents request an extension of time within which to file an answer. Therefore, I enter a default judgment against the Respondents and assess a civil money penalty of \$2,000.

CTP began this case by serving the Complaint on Respondents and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondents impermissibly sold cigarettes to a minor, failed to verify that cigarette purchaser was 18 years of age or older, and sold individual cigarettes 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 \$2,000.

On September 23, 2014, CTP served the Complaint on Respondents 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, Respondents should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondents that if they 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 Respondents to pay the full amount of the proposed penalty.

The Respondents have 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:

- Respondents own K and S Market, LLC, an establishment that sells tobacco products and is located at 604 Ferry Street, New Haven, Connecticut 06513. Complaint ¶ 3.
- During a two-part inspection of Respondents’ establishment on August 16, 2013 and August 21, 2013, at an unspecified time, an FDA-commissioned inspector observed Respondent’s staff “sell[] individual cigarettes. Complaint ¶ 10.
- On December 12, 2013, CTP issued a Warning Letter to the Respondents regarding the inspector’s observations from August 16, 2013 and August 21, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. §1140.14(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 the Respondents failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that the Respondents are responsible for complying with the law. Complaint ¶ 10.
- Karwan Sofi, Respondent’s manager, responded to the Warning Letter on the Respondents’ behalf by letter on December 19, 2013 . “Mr. Sofi stated that the Respondents discontinued the sale of individual cigarettes.” Complaint ¶ 11.
- During a subsequent inspection of Respondents’ establishment on February 28, 2014, at approximately 11:31 AM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase individual cigarettes . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 1.

These facts establish that Respondents are liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state 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 Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). The regulations prohibit the sale of cigarettes 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 cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Additionally, the regulations prohibit the sale of individual cigarettes. 21 C.F.R. § 1140.14(d).

Taking the above alleged facts as true, Respondents violated the prohibition against selling individual cigarettes, 21 C.F.R. § 1140.14(d) during a two-part inspection on August 16, 2013 and August 21, 2013, and on February 28, 2014. On February 28, 2014, the Respondents also violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a); and the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondents' actions constitute violations of law that merit a civil money penalty.

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.

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/s/  
Steven T. Kessel  
Administrative Law Judge