

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

The Kroesser Group LLC  
d/b/a DIY Tobacco,

Respondent.

Docket No. C-14-299  
FDA Docket No. FDA-2013-H-1514

Decision No. CR3113

Date: February 11, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against The Kroesser Group LLC d/b/a DIY Tobacco (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$250 civil money penalty.

CTP initiated 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's staff impermissibly sold regulated tobacco products to a person younger than 18 years of age and failed to verify that cigarette purchasers were of sufficient age, 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. Part 1140 (2012). CTP seeks a civil money penalty of \$250.

On December 13, 2013, 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 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 warned Respondent that if it failed to take one of these 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.

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 DIY Tobacco, an establishment that sells tobacco products and is located at 2600 Northwest Randall Way, Suite 111, Silverdale, Washington 98383. Complaint ¶ 3.
- On January 18, 2013, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Camel Crush Regular Fresh cigarettes . . . at approximately 10:23 AM PT[.]” The inspector also observed that “the minor’s identification was not verified before the sale . . . on January 18, 2013 . . . .” Complaint ¶ 10.
- On January 31, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 18, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), 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.

- Catherine Kroesser, Respondent’s CEO, responded to the Warning Letter in a February 12, 2013 letter. “Ms. Kroesser stated that as a result of the Warning Letter, the establishment updated its tobacco sales policy to require employees to verify the identification of all tobacco purchasers, and retrained its employees on this policy using the ‘WE CARD’ program and other resources.” Ms. Kroesser further stated “that the establishment would employ a secret shopper program to monitor employees’ compliance with its tobacco policy.” Complaint ¶ 11.
- On June 11, 2013, FDA-commissioned inspectors documented 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 Camel Crush Regular Fresh cigarettes . . . at approximately 11:29 AM.” 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 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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 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).

Taking the above alleged facts as true, Respondent committed two violations of 21 C.F.R. Part 1140 within a five-month period. Specifically, on January 18, 2013, Respondent unlawfully sold a regulated tobacco product to a minor and failed to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer’s date of birth. 21 C.F.R. § 1140.14(a) and (b)(1). On June 11, 2013, Respondent unlawfully sold a regulated tobacco product to a minor. Therefore, Respondent’s actions and omissions 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