

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Kossi Klassou / Wintergreen Mobil Inc.
d/b/a Wintergreen Mobil,

Respondent.

Docket No. C-14-854
FDA Docket No. FDA-2014-H-0372

Decision No. CR3241

Date: May 27, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Kossi Klassou / Wintergreen Mobil Inc. d/b/a Wintergreen Mobil, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$250. 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 \$250.

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 cigarettes to minors on two separate occasions, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On April 3, 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default 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. 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 Wintergreen Mobil, an establishment that sells tobacco products and is located at 890 Rockville Pike, Rockville, Maryland 20852 . Complaint ¶ 3.
- On November 16, 2012, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 3:33 PM ET.” Complaint ¶ 10.
- On December 6, 2012, CTP issued a Warning Letter to Mobil explaining that the inspector’s November 16, 2012 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a).¹ In addition to describing the violation, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violation. The letter also stated that it was Respondent’s responsibility to comply with the law. Complaint ¶ 10.

¹ In the Complaint, CTP alleges that it issued a Warning Letter to “Mobil at 890 Rockville Pike, Rockville, MD 20852.” Because this address is the same address listed for Wintergreen Mobil, I infer that CTP is referring to the same retail outlet.

- The FDA did not receive a response to the Warning Letter, but delivery records show that an individual named “Amdrave” received it on December 7, 2012. Complaint ¶ 11.
- On August 19, 2013, during a subsequent inspection of Respondent’s establishment, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 1:58 PM.” 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age.

Here, Respondent violated 21 C.F.R. § 1140.14(a) on November 16, 2012, and August 19, 2013, when its staff sold cigarettes to minors. Therefore, Respondent’s actions on two separate occasions at the same retail outlet constitute violations of law that warrant a civil money penalty. Accordingly, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge