

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Civic's Grocery Store LLC,

Respondent.

Docket No. C-14-470
FDA Docket No. FDA-2013-H-1688

Decision No. CR3197
Date: April 11, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Civic's Grocery Store LLC, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

CTP initiated 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 occasions and, during both transactions, Respondent's staff failed to verify that the cigarette purchasers were of a sufficient age, 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 \$500.

On January 23, 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 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 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 Civic’s Grocery Store LLC, an establishment that sells tobacco products and is located at 138 Cherry Street, Waterbury, Connecticut 06702. Complaint ¶ 3.
- During a May 16, 2013 inspection of Respondent’s establishment, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Maverick Menthol Box 100s cigarettes . . . at approximately 10:00 AM [] and . . . the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On May 30, 2013, CTP issued a Warning Letter to Civic’s Grocery regarding the inspector’s observations from May 16, 2013. The letter explained that the named violations were 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 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.
- Roseann Telesco responded to the Warning Letter on Respondent’s behalf in a June 14, 2013 telephone call. “Ms. Telesco stated that the establishment met with the person responsible for the store on the day of the violation and that person was made aware that selling to minors is unacceptable.” Ms. Telesco further stated that “[t]he establishment had a staff meeting with all employees and went over the violations as well as

tobacco laws and regulations. The establishment also had all employees watch the FDA Tobacco Compliance webinar for small business[es] and reminded employees if they had questions to refer to the posters in the store or to the FDA website.” Ms. Telesco also advised CTP that “the establishment planned on having monthly trainings to review laws and regulations.” Complaint ¶ 11.

- On August 13, 2013, during another 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 Marlboro Gold Pack cigarettes . . . at approximately 11:38 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer’s date of birth, that no cigarette purchasers are younger than 18 years of age.

Here, Respondent violated 21 C.F.R. § 1140.14(a) and (b)(1), on May 16, 2013, and again on August 13, 2013, when its staff sold cigarettes to minors and failed to verify that the cigarette purchasers were 18 years of age or older by checking photographic identification. Respondent’s actions and omissions constitute violations of law that warrant a civil money penalty. Accordingly, I find that a civil money penalty of \$500 is permissible under 21 C.F.R. § 17.2 and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge