

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

American Choice, LLC
d/b/a George Street Deli,

Respondent.

Docket No. C-14-1709
FDA Docket No. FDA-2014-H-1194

Decision No. CR3428

Date: October 21, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, American Choice, LLC d/b/a George Street Deli 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 a minor, failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older, and impermissibly sold individual cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its

implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$250.

On August 21, 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 issue an initial decision by default 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 George Street Deli, an establishment that sells tobacco products and is located at 802 George Street, New Haven, Connecticut 06511. Complaint ¶ 2.
- During an inspection of Respondent's establishment on August 6, 2013, at approximately 10:13 AM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes . . .[.]" The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 9.
- On November 21, 2013, CTP issued a Warning Letter to Respondent regarding the inspector's observations from August 6, 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 violation was 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 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 ¶ 9.
- By letter, on November 30, 2013, Adam Almteri, responded to the Warning Letter on Respondent's behalf. "Mr. Almteri admitted that Respondent 'sold the cigarettes to a minor without checking ID[.]'" Mr. Almteri went on to state that

“Respondent . . . will check the identification of purchasers prior to selling tobacco products.” Complaint ¶ 10.

- During a subsequent two-part inspection of Respondent’s establishment conducted on January 27, 2014 and February 3, 2014, FDA-commissioned inspectors documented a violation of 21 C.F.R. § 1140.14(d) “for selling individual cigarettes” 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). The regulations prohibit the sale of cigarettes or smokeless tobacco 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 tobacco purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Under 21 C.F.R. § 1140.14(d), retailers are prohibited from breaking or otherwise opening any cigarette package to sell or distribute individual cigarettes.

Taking the above alleged facts as true, Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 6, 2013. On that same date, Respondent violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Additionally, during a two-part inspection conducted on January 27, 2014 and February 3, 2014, Respondent violated 21 C.F.R. § 1140.14(d) by selling individual cigarettes. Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge