Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Hopkinton Gas, Inc.,

Respondent.

Docket No. C-13-1264 FDA Docket No. FDA-2013-H-1070

Decision No. CR2988

Date: November 8, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Hopkinton Gas, Inc., alleging facts and legal authority sufficient to justify imposing 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 order that Respondent pay a civil money penalty in the amount of \$500.

CTP began 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 unlawfully sold regulated tobacco products to minors on two separate occasions and failed to verify that the tobacco purchasers were of sufficient age prior to these transactions, 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 September 12, 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 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. 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 Hopkinton Gas, an establishment that sells tobacco products and is located at 1 Grove Street, Hopkinton, Massachusetts 01748. Complaint ¶ 3.
- On July 17, 2012, during an 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 Marlboro cigarettes . . . at approximately 11:06 AM ET[.]" The inspector also noted that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On October 4, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from July 17, 2012. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1). In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.
- On October 10, 2012, Respondent's manager responded in writing to the Warning Letter on Respondent's behalf. Respondent's letter "stated that the establishment identified the clerk who sold [the cigarettes] to the minor" The letter also stated that the establishment "increased signage" indicating that "proof of age is required to purchase cigarettes and that

employees are required to ask for identification in order to sell cigarettes." Complaint \P 11.

• On March 19, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. At approximately 3:56 PM ET, Respondent's staff sold a package of Marlboro cigarettes to a person younger than 18 years of age. In addition, Respondent's staff did not verify the tobacco purchaser's age by checking the minor's photo identification prior to this 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), retailers are prohibited from selling cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photo identification containing the bearer's date of birth, that cigarette purchasers are 18 years of age or older.

Here, Respondent's staff sold cigarettes to minors, in violation of 21 C.F.R. § 1140.14(a), on two separate occasions: July 17, 2012, and March 19, 2013. Prior to these transactions, Respondent's staff did not verify, by checking the cigarette purchaser's photographic identification, that the cigarette purchaser was 18 years of age or older, as required by 21 C.F.R. § 1140.14(b)(1). Respondent's actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$500 is permissible under 21 C.F.R. § 17.2 and order one imposed.

/s/

Steven T. Kessel Administrative Law Judge