

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Duffy and Associates, Inc. and Lee Duffy
d/b/a Discount Tobacco,

Respondent.

Docket No. C-15-1487
FDA Docket No. FDA-2015-H-0670

Decision No. CR4180

Date: August 28, 2015

INITIAL DECISION

I sustain the determination of the Center for Tobacco Products of the United States Food and Drug Administration (CTP) to impose a civil money penalty of \$500 against Respondent Duffy and Associates, Inc. and Lee Duffy d/b/a Discount Tobacco. The preponderance of the evidence establishes that Respondent distributed free samples of cigarettes, unlawfully sold tobacco products (cigarettes) to a minor, and failed to verify that the cigarette purchaser was 18 years of age or older during a twenty-four month period in violation of 21 C.F.R. §§ 1140.16(d)(1), 1140.14(a), and 1140.14(b)(1). These actions were violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 387c(a)(7)(B).

I. Procedural History

Complainant began this matter by serving an administrative complaint on Respondent, Discount Tobacco, at 1726 East Sangamon Avenue, Springfield,

Illinois 62702, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered the Complaint. In its Answer, Respondent provided a picture of the individual that it believes was the alleged minor. Respondent denied selling tobacco products to a minor, and further stated that the verification of photographic identification was not required for persons over the age of 26, and Respondent believed that the alleged minor was over 26.

On March 27, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges. The Complainant filed its pre-hearing exchange on June 19, 2015. Complainant's filing included an informal brief, a witness and exhibit list and the submission of 28 Exhibits that are identified as CTP Ex. 1 – CTP Ex. 28. Complainant alleged in its brief that Respondent distributed free samples of cigarettes, unlawfully sold cigarettes to a minor, and failed to verify that the cigarette purchaser was 18 years of age or older. Complainant also asserts that the assessment of a \$500 civil money penalty is appropriate.

Respondent subsequently filed its pre-hearing exchange July 9, 2015. Respondent's filing included an informal brief, a witness and exhibit list, and the submission of 8 Exhibits that are identified as R. Ex. 1 – R. Ex. 8. In its informal brief, Respondent admitted to the distribution of free samples of tobacco products on March 31, 2014. Respondent asserted that it did not have the evidence to confirm or deny whether it sold cigarettes to a minor. Respondent submitted a photograph of the individual that it believes was the alleged minor and stated that “[i]f the photo confirms the identity of the alleged minor, and said person is confirmed to be a minor, then we accept the allegation as true.” Then, assuming the submitted photograph was of the alleged minor, the individual who sold the cigarettes “solemnly [swears] before the courts that said person did not appear to be under the age of 27.” Respondent also takes issue with the amount of the civil money penalty because it does not believe that it failed to verify the identification of the cigarette purchaser.

I held a pre-hearing conference on August 3, 2015, following which both parties informed me that they did not intend to cross-examine the other party's witness(es). I am issuing a decision on the record in this case. I admit into evidence the Complainant's exhibits identified as CTP Ex. 1 – CTP Ex. 28, and the Respondent's exhibits identified as R. Ex. 1 – R. Ex. 8.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether: Respondent distributed free samples of cigarettes, unlawfully sold tobacco products (cigarettes) to a minor, and failed to verify that the cigarette purchaser was 18 years of age or older; and whether the law authorizes the remedy imposed by CTP.

B. Findings of Fact and Conclusions of Law

The following facts are either undisputed or are established by the preponderance of the evidence. Respondent does business as Discount Tobacco, located at 1726 East Sangamon Avenue, Springfield, Illinois 62702. Respondent's business includes the sale of tobacco products, including cigarettes. CTP Informal Brief, at 3-5; Respondent Informal Brief, at 1-2.

i. Distribution of Free Samples of Cigarettes

Complainant alleges that Respondent distributed free samples of cigarettes on March 31, 2014. Complaint ¶ 10. Respondent admits that Complainant's allegation is true. Respondent Informal Brief, at 3.

ii. Unlawful Sale of Tobacco Products to a Minor

On October 17, 2014, two inspectors working on behalf of CTP conducted an undercover buy inspection at Respondent's business. CTP Ex. 1; CTP Ex. 2. One of the inspectors entered Respondent's business and the other inspector waited in the vehicle during the undercover buy inspection. The inspectors brought with them a minor. The minor purchased Marlboro cigarettes from an employee of Respondent's business.

Respondent states that it does not have evidence to confirm or deny whether this allegation is true. Respondent provides a photograph of a customer and states that if that photograph is of the alleged minor then it accepts that the Complainant's allegation is true. I find it unnecessary to determine whether Respondent's photograph is of the alleged minor. Respondent provides no evidence that it did not sell cigarettes to a minor, and Complainant has provided declarations that support its assertion that the sale occurred. Governing regulations prohibit the sale of tobacco products to any person who is under the age of 18. 21 C.F.R. § 1140.14(a). The evidence proves that Respondent violated that regulation on October 17, 2014, when its employee sold cigarettes to a minor. This violation is in turn a violation of the Act, 21 U.S.C. §§ 331k and 387c(a)(7)(B).

iii. Failure to Verify that Cigarette Purchaser Was 18 Years of Age Or Older

Complainant also alleges that Respondent failed to verify that the cigarette purchaser was 18 years of age or older. On October 17, 2014, the minor carried with her identification establishing her actual date of birth. CTP Ex. 1; CTP Ex. 2. On the occasion of the purchase, the employee of Respondent did not ask the minor for identification, and the minor did not provide identification. CTP Ex. 1.

Respondent states that, assuming the minor is the person in the photograph, the minor does not appear to be under the age of 27, and that Food and Drug Administration guidance states that the photographic identification of those who appear to be under the age of 27, who attempt to purchase tobacco products, should be checked. Respondent Informal Brief.

The governing regulation states that “each retailer shall verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the product is younger than 18 years of age.” 21 C.F.R. § 1140.14(b)(1). The regulation further states that “[n]o such verification is required for any person over the age of 26.” 21 C.F.R. § 1140.14(b)(2). The regulation requires Respondent to verify the date of birth of the purchaser if they are 26 years of age or younger. This was an objective requirement, and was not intended to allow retailers to forego age verification based on an employee’s subjective determination of the purchaser’s age. *See* 61 Fed. Reg. 44396, at 44439 (August 28, 1996) (“By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.”). The evidence proves that Respondent violated that regulation on October 17, 2014, when its employee failed to verify that the minor cigarette purchaser was 18 years of age or older. This violation is in turn a violation of the Act, 21 U.S.C. §§ 331k and 387c(a)(7)(B).

iv. Appropriateness of the Penalty

Complainant is authorized to impose civil money penalties on individuals or entities that violate the Act and its implementing regulations. Penalties of up to \$500 are authorized for three violations that occur within a 24-month period. 21 C.F.R. § 17.2. I find that the penalty that Complainant seeks to impose for Respondent’s noncompliance is reasonable pursuant to 21 U.S.C. § 333(f)(5)(B). The amount of the penalty is minimal. Respondent’s noncompliance, however, is egregious. The evidence in this case establishes that Respondent distributed free samples of cigarettes, sold cigarettes to a minor, and failed to verify that the cigarette purchaser was 18 years of age or older. I note, furthermore, that

Respondent presented no evidence to establish that it would suffer any hardship as a result of being subject to the minimal penalty that CTP requests. For these reasons, I sustain the penalty amount.

Order

For these reasons, I enter judgment in the amount of \$500 against Respondent Duffy and Associates, Inc. and Lee Duffy d/b/a Discount Tobacco.

/s/

Steven T. Kessel
Administrative Law Judge