Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

G and L Foodmart, Inc. d/b/a Food Mart,

Respondent.

Docket No. C-14-595 FDA Docket No. FDA-2014-H-0128

Decision No. CR3182

Date: March 31, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against G and L Foodmart, Inc. d/b/a Food Mart (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent utilized self-service displays to sell regulated tobacco products in a non-exempt facility, Respondent's staff unlawfully sold cigarettes to minors on two occasions, and 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), codified at 21 U.S.C. §§ 301 – 399d, and its implementing regulations, found at 21 C.F.R. Part 1140.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on February 11, 2014, via United Parcel Service. The Complaint and accompanying cover letter stated 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 neither filed an Answer within the time provided by regulation, nor timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to "assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act]," issue an initial decision and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Food Mart, an establishment that sells tobacco products and is located at 3308 East 32nd Street, Joplin, Missouri 64804. Complaint ¶ 3.
- On May 10, 2013, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Red Seal Long Cut Wintergreen smokeless tobacco... at approximately 5:23 PM[.]" The inspector also observed that "the minor's identification was not verified before the sale ... on May 10, 2013"¹ Complaint ¶ 10.

¹ The complaint alleges that Respondent first violated the Act on May 10, 2013, at approximately 5:23 PM, when Respondent's staff "[sold] tobacco products to a minor," and that Respondent violated the Act a second time on May 10, 2013, at approximately 4:21 PM, when "the minor's identification was not verified before the sale, *as detailed above*" (emphasis added). That the second violation occurred nearly one hour prior to the first seems highly unlikely. Therefore, I infer that this is a typographical error. I am satisfied that these two violations occurred and that CTP's allegations satisfy the requirements for imposing a \$500 penalty.

- On May 30, 2013, CTP issued a Warning Letter to Food Mart regarding the inspector's observation from May 10, 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.
- Although United Parcel Service records indicate that an individual named "Mitchell" received the warning letter on May 31, 2013, the FDA did not receive a response to the warning letter. Complaint ¶ 11.
- During a subsequent inspection conducted on October 18, 2013, FDAcommissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. Specifically, "a person younger than 18 years of age was able to purchase a package of Pall Mall Red cigarettes on October 18, 2013, at approximately 4:21 PM[.] The inspectors also observed Respondent "[u]sing a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c)." Particularly, the facility had "multiple brands of smokeless tobacco and packages of Bugler Turkish cigarette tobacco located on shelves directly in front of the sales counter. Additionally, there were two displays containing various brands of smokeless tobacco located on the sales counter [which were] directly accessible to customers." During the inspection, "Daniel Graves ... Respondent's owner, told the inspector that the establishment [was] open to the public[,] [therefore,] the displays were located in a customeraccessible area of the establishment, in which "minors [were] permitted to enter at any time." Complaint ¶ 1.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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, codified at 21 U.S.C. § 387f(d). *See* 21 U.S.C. § 387(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). Retailers are required to verify, by means of photo identification containing the purchaser's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Self-service displays are a

method of sale that is not permitted under the regulations, 21 C.F.R. 1140.16(c)(1), except when located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii).

In the present case, on May 10, 2013, Respondent sold a regulated tobacco product to a person younger than 18 years of age, and failed to verify, by means of photo identification, that the purchaser was 18 years of age or older in violation of 21 C.F.R. § 1140.14(a) and (b)(1). On October 18, 2013, Respondent utilized selfservice displays in violation of 21 C.F.R. § 1140.16(c), and sold a regulated tobacco product to a person younger than 18 years of age. Therefore, Respondent's actions and omissions constitute violations of law that warrant a civil money penalty. Accordingly, I find that a civil money penalty in the amount of \$500 is permissible under 21 C.F.R. § 17.2.

/<u>s/</u> Steven T. Kessel Administrative Law Judge