

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Manchester Food Store, Inc.
d/b/a Krauszer's Food Stores & Deli,

Respondent.

Docket No. C-13-474
FDA Docket No. FDA-2013-H-0237

Decision No. CR2753

Date: April 11, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Manchester Food Store, Inc. d/b/a Krauszer's Food Stores & Deli, that alleges 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 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 impermissibly sold tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser through photographic identification on both of those occasions, 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 for these violations.

On March 4, 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, the Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or 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 a default judgment 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 Krauszer’s Food Stores & Deli, an establishment that sells tobacco products and is located at 305 Green Road, Manchester, Connecticut 06042.
- On June 5, 2012, an FDA-commissioned inspector observed that Respondent sold tobacco products to a minor and failed to verify the purchaser’s age before the sale.
- “[O]n August 2, 2012, CTP issued a Warning Letter to Krauszer’s Food Stores & Deli.” Complaint ¶ 10. The letter informed Respondent of the violations that the FDA-commissioned inspector had observed on June 5, 2012, and that the failure to correct violations could result in the imposition of a civil money penalty or other regulatory action. Moreover, the letter informed Respondent that the warning was not intended to provide an exhaustive list of violations and that Respondent maintained the responsibility to ensure that it complied with the law.
- Respondent provided a written response to CTP’s warning letter on August 8, 2012. Respondent informed CTP that the store would “train employees to check photo ID before selling tobacco products to anyone under twenty-seven, and that the establishment’s POS system would show a red flag

before selling tobacco products to anyone under twenty-seven.” Complaint ¶ 11.

- On September 25, 2012, CTP acknowledged in writing that it had received Respondent’s response and reminded Respondent that it had a continuing duty to comply with the Act and implementing regulations.
- Pursuant to a two-part inspection conducted on October 23, and 31, 2012, FDA-commissioned inspectors noted that “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes on October 23, 2012, at approximately 12:44 PM ET[,]” in violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 1(a).
- Further, the inspectors noted that “the minor’s identification was not verified before the [October 23, 2012] sale,” in violation of 21 C.F.R. § 1140.14(b)(1). Complaint ¶ 1(b).
- On November 2, 2012, CTP informed Respondent of the October 23, 2012, inspector-documented violation through a Notice of Compliance Check Inspection. The notice additionally informed Respondent “that other potential violations of federal tobacco law may have been observed” and that FDA may notify Respondent if CTP determined violations had occurred. Complaint ¶ 2.

Taking these facts as true, I must find pursuant to 21 C.F.R. § 17.11(a) 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those 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). Those regulations also require a retailer to “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), though “[n]o such verification is required for any person over the age of 26[,]” 21 C.F.R. § 1140.14(b)(2).

Here, Respondent sold tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser on both of those occasions in violation of the foregoing regulations. Respondent’s actions and omissions constitute violations of law for which a civil money penalty is merited. The regulations require the imposition of a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the complaint, whichever

