

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

James Leach and Ina Leach
d/b/a Livonia Mini Mall,

Respondent.

Docket No. C-13-152
FDA Docket No. FDA-2012-H-1175

Decision No. CR2685

Date: January 11, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority that are sufficient to justify the imposition of 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, James Leach and Ina Leach d/b/a Livonia Mini Mall, 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 utilized methods of sale other than direct, face-to-face exchanges; failed to ensure that all non-compliant self-service displays and other items were removed or brought into compliance with the regulations; impermissibly sold tobacco products to a minor; and failed to verify the age of a person purchasing tobacco products.

The complaint further alleges that these actions and omissions violated 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 December 5, 2012, 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

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 establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Livonia Mini Mall, an establishment that sells tobacco products and is located at 202 South Main Street, Livonia, Missouri.
- On January 4, 2012, an FDA-commissioned inspector observed violations at Livonia Mini Mall that included: the failure to sell cigarettes or smokeless tobacco only in a direct, face-to-face sale in a non-exempt establishment, in violation of 21 C.F.R. § 1140.16(c)(1) and 1140.16(c)(2)(ii); and the failure to either remove or bring into compliance all non-compliant items, such as self-service displays, advertising, and labeling, in violation of 21 C.F.R. § 1140.14(e).
- CTP issued a warning letter to Respondent on February 16, 2012, informing Respondent of the violations observed on January 4, 2012. The letter advised that the failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action, that it was not intended to provide an exhaustive list of violations, and that Livonia Mini Mall had the responsibility to ensure it complied with the law.
- The warning letter was delivered via United Parcel Service on February 17, 2012, to “Hines,” but CTP receive no response.

- On June 7 and 11, 2012, FDA-commissioned inspectors conducted a two-part inspection and noted additional violations. The inspectors documented that “a person younger than 18 years of age was able to purchase a package of Copenhagen Long Cut smokeless tobacco on June 7, 2012, at approximately 12:52 PM CT[,]” a violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 1.a. The inspectors further documented a violation of 21 C.F.R. § 1140.14(b)(1) because “the minor’s identification was not verified before the sale[.]” Complaint ¶ 1.b.
- CTP notified Livonia Mini Mall on June 15, 2012, of the violations documented on June 7, 2012, through a Notice of Compliance Check Inspection. CTP warned that the inspectors may have observed other violations and, if violations had occurred, the establishment would be informed that the FDA was seeking a fine.

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). The 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). The regulations further prohibit the sale of tobacco products other than through face-to-face exchanges, 21 C.F.R. § 1140.16(c)(1), except “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 addition, the regulations require retailers to remove or bring into compliance all non-compliant “self-service displays, advertising, labeling, and other items, that are located in the retailer’s establishment.” 21 C.F.R. § 1140.14(e).

Here, Respondent sold tobacco products in violation of each of the foregoing regulations. These actions and omissions by Respondent constitute violations of law for which a civil money penalty is merited. The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed four violations within a 24-month period, the maximum penalty for which is \$2,000. 21 C.F.R. § 17.2; *Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (Revised)*, November 2012, (available at

