

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Luisa Deli and Grocery Inc.  
d/b/a Luisa Grocery,

Respondent.

Docket No. C-13-1208  
FDA Docket No. FDA-2013-H-1003

Decision No. CR2996

Date: November 15, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Luisa Deli and Grocery Inc. d/b/a Luisa Grocery, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not 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 \$2,000.

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 impermissibly sold cigarettes to a minor, failed to verify that a cigarette purchaser was 18 years of age or older, and sold individual cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations,

Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$2,000.

On September 24, 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 proposed 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 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 “assume the facts alleged in the [C]omplaint to be true” and, if those 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 the following facts in its Complaint:

- Respondent owns Luisa Grocery, an establishment that sells tobacco products and is located at 123 Elizabeth Avenue, Newark, New Jersey 07108. Complaint ¶ 3.
- On February 11, 2013, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(d) “for selling individual cigarettes . . . .”<sup>1</sup> Complaint ¶ 10.
- On February 28, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 11, 2013. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(d), and that the named violation was not necessarily

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<sup>1</sup> The regulation prohibits retailers from “*break[ing] or otherwise open[ing] any cigarette or smokeless tobacco package* to sell or distribute individual cigarettes . . . . [.]” 21 C.F.R. § 1140.14(d) (emphasis added). CTP, however, alleges only that Respondent sold individual cigarettes “in violation of 21 C.F.R. § 1140.14(d),” and fails to allege that Respondent either broke open a package of cigarettes or that the individual cigarettes visibly came from an opened package. Because Respondent did not answer CTP’s Complaint, I will infer that both elements of a violation of 21 C.F.R. § 1140.14(d) are present.

intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, 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.

- Juan Rivas, Respondent’s owner, responded to the Warning Letter with a June 6, 2013 letter of his own. “Mr. Rivas stated that the establishment: 1) is retraining employees; 2) will check the photo identification of everyone appearing to be under the age of 27 who attempts to purchase tobacco products; 3) will sell tobacco products only to purchasers 18 years and older; and 4) will only sell tobacco products in direct, face-to-face exchanges.” Complaint ¶ 11.
- On June 12, 2013, at approximately 2:51 PM, FDA-commissioned inspectors documented three additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspectors documented violations of 21 C.F.R. § 1140.14(a) and (d) when “a person younger than 18 years of age was able to purchase individual cigarettes . . . [.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale . . . .” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Luisa Grocery on June 17, 2013, due to the June 12, 2013 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 2:51 PM” on June 12, 2013. Complaint ¶ 2.

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 distributed or offered for sale in any state 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). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from breaking or otherwise opening cigarette packages in order to sell individual cigarettes. 21 C.F.R. § 1140.14(d).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a four-month period. Specifically, Respondent had a violation on February 11, 2013, and three violations on June 12, 2013. Respondent's actions on June 12, 2013, violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions on June 12, 2013, also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, Respondent's actions on both February 11, 2013, and June 12, 2013, violated the prohibition against breaking open a package of cigarettes in order to sell individual cigarettes. 21 C.F.R. § 1140.14(d). Therefore, Respondent's actions constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in an 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)(1)-(2). The regulations currently allow a maximum penalty of \$2,000 for a fourth violation within a four-month period, 21 C.F.R. § 17.2, and CTP has requested a fine in that amount. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

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/s/  
Steven T. Kessel  
Administrative Law Judge