

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Luisa Deli and Grocery, Inc. / Juan G. Rivas
d/b/a Luisa Grocery,

Respondent.

Docket No. C-15-112
FDA Docket No. FDA-2014-H-1614

Decision No. CR3513

Date: January 27, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Luisa Deli and Grocery, Inc. / Juan G. Rivas d/b/a Luisa Grocery, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$10,000. 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 \$10,000.

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 minors, failed to verify that cigarette purchasers were 18 years of age or older and distributed 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. pt. 1140 (2013). CTP seeks a civil money penalty of \$10,000.

On October 22, 2014, 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.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-13-1208, FDA Docket Number FDA-2013-H-1003, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) on June 12, 2013 by selling tobacco products to a minor. On June 12, 2013, Respondent also violated 21 C.F.R. § 1140.14(b) by failing to verify, by means of photographic identification containing the purchaser’s date of birth, that the purchaser of cigarettes was not younger than 18 years of age. Respondent also violated 21 C.F.R. § 1140.14(d) by selling individual cigarettes on June 12, 2013 and February 11, 2013. Complaint ¶ 10.
- The previous civil money penalty action concluded when on November 15, 2013 an administrative law judge issued an Initial Decision and Default Judgment against Respondent. This decision, which became final and binding on December 15, 2013, found Respondent liable for the four violations. Complaint ¶ 11-12.
- During a subsequent inspection of Respondent’s establishment conducted on May 1, 2014, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase an individual cigarette. . . at approximately 7:03 PM[.]” The inspectors also noted that “the minor’s identification was not verified before the sale . . . [.]” Complaint ¶ 1.

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

