

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Maria E. Cintron  
d/b/a DR Grocery II,

Respondent.

Docket No. C-15-400  
FDA Docket No. FDA-2014-H-1935

Decision No. CR3581

Date: January 21, 2015

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Maria E. Cintron, d/b/a DR Grocery II that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$5,000. 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 \$5,000.

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 and failed to verify that cigarette purchasers were 18 years of age or older, 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 \$5,000.

On November 20, 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 DR Grocery II, an establishment that sells tobacco products and is located at 71 Washington Street, Waterbury, Connecticut 06706. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-885, FDA Docket Number FDA-2014-H-0387, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, those violations included violations on May 22, 2013 and September 20, 2013, when Respondent sold tobacco products to a minor and failed to verify the age of the tobacco purchaser by means of a photographic identification. Complaint ¶ 10.
- The previous action concluded when Maria Cintron, Respondent’s authorized representative, settled the claims on Respondent’s behalf. On May 1, 2014, Ms. Cintron signed an Acknowledgment Form in which she “admitt[ed] that the violations . . . occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions.” The Administrative Law Judge closed the case on May 14, 2014. Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on May 30, 2014, at approximately 12:53 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes. . . [.]” The inspectors also documented 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

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 of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 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 purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 20, 2013, September 20, 2013, and May 30, 2014. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$5,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed.

                        /s/                          
Steven T. Kessel  
Administrative Law Judge