

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

George's Grocery USA, LLC
d/b/a George's USA,

Respondent.

Docket No. C-15-605
FDA Docket No. FDA-2014-H-2131

Decision No. CR3613

Date: February 2, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, George's Grocery USA, LLC d/b/a George's USA, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$11,000. 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 order that Respondent pay a civil money penalty in the amount of \$11,000.

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's staff unlawfully sold tobacco products to a minor, sold an individual cigarette, and failed to verify, by means of photo identification containing a date of birth, that a tobacco purchaser was 18 years of age or older,

thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$11,000.

On December 10, 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 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has not filed an answer or any other pleading within the time prescribed. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns George's USA, an establishment that sells tobacco products and is located at 2509 Main Street, Bridgeport, Connecticut 06606. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-1057, FDA Docket Number FDA-2014-H-0579, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, those violations included unspecified violations¹ on June 11, 2013, and three violations during inspections on October 7, 2013 and October 9, 2013, when Respondent sold tobacco products to a minor, made individual cigarettes available for sale, and failed to verify, by means of photographic identification, that a tobacco purchaser was 18 years of age or older. Complaint ¶ 10; May 12, 2014 Complaint ¶ 1.
- The previous civil money penalty action concluded when Ramez Lahham, Respondent's authorized representative, settled the action with CTP on

¹ In the complaint, CTP describes the actions that took place at Respondent George's Grocery USA, LLC d/b/a George's USA's business establishment on June 11, 2013, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint initiated on May 12, 2014, and attached to the present complaint, CTP described two discrete violations at Respondent George's Grocery USA, LLC d/b/a George's USA's business establishment on June 11, 2013: a violation of 21 C.F.R. § 1140.14(a) and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on June 11, 2013, was a typographical error.

Respondent's behalf. On June 25, 2014, Mr. Lahham signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] Respondent's ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions against Respondent." The Administrative Law Judge closed the case on July 16, 2014. Complaint ¶ 11.

- During a subsequent inspection of Respondent's establishment conducted on August 19, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase an individual cigarette . . . at approximately 11:55 AM[.]" The inspectors also noted that "the minor's identification was not verified before the sale . . . [.]" Complaint ¶ 1.
- The findings documented at the August 19, 2014 inspection comprise three additional incidents of noncompliance in addition to the four documented previously and admitted to by Respondent.

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 sold or distributed 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 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 the verification, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from breaking or otherwise opening a cigarette package in order to sell individual cigarettes. 21 C.F.R. § 1140.14(d).

Here, Respondent had seven violations of regulations found at 21 C.F.R. pt. 1140 within a 48-month period. Respondent acknowledged that three violations occurred when its representative settled the previous civil money penalty action. Most recently, during an inspection on August 19, 2014, Respondent sold an individual cigarette to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a) and (d). On that same date, Respondent violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchaser is 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.

