Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Thais Mini Market Inc. d/b/a I and S Grocery Inc.,

Respondent.

Docket No. C-15-175 FDA Docket No. FDA-2014-H-1691

Decision No. CR3524

Date: December 22, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Thais Mini Market Inc. d/b/a I and S Grocery Inc., alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$10,000. 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 \$10,000.

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 individual cigarettes to a minor, 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 \$10,000.

On October 29, 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 (ALJ) 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 I and S Grocery Inc., an establishment that sells tobacco products and is located at 490 Avon Avenue, Newark, New Jersey 07108. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-13-588, FDA Docket Number FDA-2013-H-0367, against Respondent for four violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, those violations included violations¹ on June 9, 2012, and three violations on January 17, 2013, when Respondent sold individual cigarettes to a minor and failed to verify, by means of photographic identification, that the tobacco purchaser was 18 years of age or older. Complaint ¶ 10.
- The previous civil money penalty action concluded on May 21, 2013, when the ALJ issued an Initial Decision and Default Judgment finding the Respondent liable for the violations. The decision became final and binding on June 20, 2013. Complaint ¶ 11.

¹ In the complaint, CTP describes the actions that took place at Respondent's business establishment on June 9, 2012, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint initiated on April 1, 2013, and attached to the present complaint, CTP described two discrete violations at Respondent's business establishment on June 9, 2012: 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 9, 2012, was a typographical error.

• During a subsequent inspection of Respondent's establishment conducted on May 3, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase two individual cigarettes . . . at approximately 11:33 AM[.]" 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 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. An ALJ imposed a civil money penalty of \$2,000 against Respondent on May 21, 2013, finding that Respondent previously committed four violations of the Act. Most recently, on May 3, 2014, Respondent sold individual cigarettes 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.

CTP has requested a fine of \$10,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$10,000 is warranted and so order one imposed.

/s/

Steven T. Kessel Administrative Law Judge