Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Asia Supermarket, LLC d/b/a Wallingford Food Land,

Respondent.

Docket No. C-15-514 FDA Docket No. FDA-2014-H-2034

Decision No. CR3590

Date: January 22, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Asia Supermarket, LLC d/b/a Wallingford Food Land, 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 December 3, 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 Wallingford Food Land, an establishment that sells tobacco products and is located at 250 South Colony Road, Wallingford, Connecticut 06492.. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-13-1188, FDA Docket Number FDA-2013-H-0974, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 24-month period. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) on August 22, 2012 and February 25, 2013 by selling tobacco products to a minor. Respondent also violated 21 C.F.R. § 1140.14(b) on February 25, 2013 by failing to verify the minor's identification before the sale. Complaint ¶ 10; August 28, 2013 Complaint ¶ 10.
- The previous civil money penalty action concluded when on October 31, 2013 an administrative law judge issued an Initial Decision and Default Judgment against Respondent. This decision, which became final and binding on December 2, 2013, found Respondent liable for the three violations. Complaint ¶ 11;
- During a subsequent inspection of Respondent's establishment on June 3, 2014, at approximately 3:16 PM, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Skoal Long Cut Classic Wintergreen smokeless tobacco . . . [.]" 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 tobacco 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 tobacco 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 tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 22, 2012, February 25, 2013 and June 3, 2014. On February 25, 2013 and June 3, 2014, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco 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