

**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-13-1188  
FDA Docket No. FDA-2013-H-0974

Decision No. CR2977

Date: October 31, 2013

**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 \$500. 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 \$500.

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 tobacco products to minors and failed to verify that a tobacco product purchaser was 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. Part 1140 (2012). CTP seeks a civil money penalty of \$500.

On August 28, 2013, 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.

On September 27, 2013, Respondent requested additional time within which to file an answer. Respondent's representative stated that he had difficulties with the Civil Remedies Division's electronic filing system and did not have the appropriate equipment needed to participate in that system. I granted Respondent's request for an extension on September 30, 2013, and gave Respondent until October 7, 2013, to file an answer.

Respondent has not filed an answer within the additional time I provided. 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.
- On August 22, 2012, at approximately 2:40 PM ET, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at Respondent's establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(a) when "a person younger than 18 years of age was able to purchase a package of Maverick Box cigarettes . . . ." Complaint ¶ 10.
- CTP issued a Notice of Compliance Check Inspection to Wallingford Food Land on August 27, 2012, due to the August 22, 2012 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that "a minor was able to . . . purchase a regulated tobacco product at approximately 2:40 PM" on August 22, 2012. Complaint ¶ 10.

- On November 8, 2012, CTP issued a Warning Letter to Respondent regarding the inspector's observations from August 22, 2012. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- Mr. Alam responded to the Warning Letter for Respondent in a March 25, 2013 telephone call. "Mr. Alam said he spoke with each employee regarding the letter, he understood the law, and he would speak to each employee to make sure they complied." Complaint ¶ 11.
- Mr. Alam's response came, however, after FDA-commissioned inspectors had already documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. On February 25, 2013, at approximately 1:30 PM ET, inspectors documented a violation of 21 C.F.R. § 1140.14(a) when "a person younger than 18 years of age was able to purchase a package of Gambler Premium Light cigarette tobacco . . . [.]". The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when "the minor's identification was not verified before the sale . . . ." Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Wallingford Food Land on March 1, 2013, due to the February 25, 2013 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that "a minor was able to . . . purchase a regulated tobacco product at approximately 1:30 PM" on February 25, 2013. Complaint ¶ 2.

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 issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes or smokeless 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 cigarette or smokeless 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 had three violations of regulations contained in 21 C.F.R. Part 1140 within a six-month period. Specifically, Respondent had a violation on August 22, 2012, and two violations on February 25, 2013. Respondent's actions on both occasions violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions on February 25, 2013, also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$500 for a third violation within a six-month period, 21 C.F.R. § 17.2, and CTP has requested a fine in that amount. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

      /s/      

Steven T. Kessel

Administrative Law Judge