## **Department of Health and Human Services**

## DEPARTMENTAL APPEALS BOARD

## **Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

The Smoke House LLC,

Respondent.

Docket No. C-14-1276 FDA Docket No. FDA-2014-H-0774

Decision No. CR3326

Date: August 12, 2014

## INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, The Smoke House LLC, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$250.

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 a minor, failed to verify that a cigarette purchaser was 18 years of age or older, and impermissibly utilized a self-service display of smokeless tobacco, 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 \$250.

On June 19, 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 The Smoke House, an establishment that sells tobacco products and is located at 6301 Rainier Avenue South, Suite 1, Seattle, Washington 98118. Complaint ¶ 2.
- During an inspection of Respondent's establishment on February 24, 2013, at approximately 1:35 PM PT, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]" The inspector also observed that "the minor's identification was not verified before the sale . . . ." Complaint ¶ 9.
- On March 14, 2013, CTP issued a Warning Letter to Respondent regarding the inspector's observations from February 24, 2013. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were 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 violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 9.
- Saif Shmed, Respondent's owner, responded to the Warning Letter in an April 3, 2013 letter. "Mr. Shmed stated that Respondent took disciplinary action against the employee who sold the tobacco product to the minor, that all employees will request identification from every tobacco purchaser, and that Mr. Shmed will

explain to every new employee the importance of verifying identification of tobacco purchasers." Complaint  $\P$  10.

• During a subsequent inspection of Respondent's establishment on January 8, 2014, FDA-commissioned inspectors documented the presence of "two displays containing various brands of smokeless tobacco that were directly accessible to customers" in the establishment. Further, Respondent's owner "stated that minors are allowed in the establishment." 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 issued the regulations at 21 C.F.R. pt. 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 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). Finally, the regulations prohibit the use of self-service displays of smokeless tobacco, 21 C.F.R. § 1140.16(c), except in facilities in which no minors are present or permitted to enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

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 February 24, 2013. On the same date, 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). On January 8, 2014, Respondent violated the prohibition on using self-service displays as a means of selling smokeless tobacco, 21 C.F.R. § 1140.16(c), because Respondent permitted minors to enter its establishment. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/ Steven T. Kessel Administrative Law Judge