

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Vijay Patel

d/b/a BP Express Discount Tobacco Outlet,

Respondent.

Docket No. C-14-112

FDA Docket No. FDA-2013-H-1241

Decision No. CR3060

Date: January 3, 2014

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Vijay Patel d/b/a BP Express Discount Tobacco Outlet, 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 initiated 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 utilized self-service displays to offer tobacco products for sale in a customer accessible portion of the retail outlet, 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. CTP seeks a civil money penalty of \$250.

On November 6, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), 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 complaint to be true, and, if such facts establish liability under [the Act],” issue an initial decision 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 BP Express Discount Tobacco Outlet, an establishment that sells tobacco products and is located at 1274 West Highway 25/70, Newport, Tennessee 37821. Complaint ¶ 2.
- On August 23, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.16(c) at Respondent’s establishment. Specifically, Respondent “had self-service displays of smokeless tobacco in customer accessible portions of the establishment, [which were] open to person[s] of all ages.” Complaint ¶ 9.
- On November 29, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from August 23, 2012. The letter explained that the observation constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter also stated 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 ¶ 9.

- Although UPS records indicate that an individual named “Patel” received the Warning Letter on November 30, 2012, the FDA did not receive a response to the Warning Letter. Complaint ¶ 10.
- During a subsequent two-part inspection conducted on April 13, 2013, and April 23, 2013, an FDA-commissioned inspector documented an additional violation of 21 C.F.R. Part 1140 at Respondent’s establishment. Specifically, the inspector “documented a violation for using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c).” The inspector documented that Respondent “ha[d] a self-service display of smokeless tobacco in a customer accessible portion of the establishment, [which was] open to person[s] of all ages.” 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. 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 require retailers to sell cigarettes exclusively in face-to-face exchanges, without the use of devices such as vending machines, 21 C.F.R. § 1140.14(c), except where the establishment does not permit any person younger than 18 years of age to be present or enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent committed two violations of the regulations contained in 21 C.F.R. Part 1140 within an eight-month period. First, on August 23, 2012, and subsequently during a two-part inspection conducted on April 13, 2013, and April 23, 2013, Respondent impermissibly utilized self-service displays to offer smokeless tobacco products for sale in a customer-accessible portion of the retail outlet. The retail outlet was also open to persons of all ages on those dates. Therefore, Respondent has committed violations of law that merit a civil money penalty.

The regulations require me to impose a civil money penalty in an 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 \$250 for a second violation within an eight-month period, 21 C.F.R. § 17.2, and CTP has requested a fine of that amount.

