

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Satsang, Incorporated
d/b/a I-40 BP,

Respondent.

Docket No. C-14-1647
FDA Docket No. FDA-2014-H-1141

Decision No. CR3404

Date: October 6, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Satsang, Incorporated d/b/a I-40 BP, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$5,000. 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 \$5,000.

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 cigarettes to a minor and failed to verify that a cigarette purchaser was of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. In a previous civil money penalty action, I found that Respondent committed four violations of the regulations found at

21 C.F.R. pt. 1140. *Satsang, Inc. d/b/a I-40 BP*, DAB CR2997, at 3 (2013). CTP seeks a civil money penalty of \$5,000.

On August 11, 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 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 within the time provided by regulation, nor has it requested an extension. 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-40 BP, an establishment that sells tobacco products and is located at 1045 South Willow Avenue, Cookeville, Tennessee 38501. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-13-1362, FDA Docket Number FDA-2013-H-1177, against Respondent for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period. Specifically, those violations included an unspecified violation on April 30, 2011, and two violations on March 26, 2013, when Respondent sold tobacco products to a minor and failed to verify, by means of photographic identification, that the purchaser was 18 years of age or older. Complaint ¶ 10.
- The previous civil money penalty action concluded when I issued an Initial Decision and Default Judgment against the Respondent on November 19, 2013, and found Respondent to have committed four violations of the regulations found at 21 C.F.R. pt. 1140. Complaint ¶ 11; *Satsang, Inc.*, DAB CR2997 at 3.
- During a subsequent inspection of Respondent's establishment conducted on February 15, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . at approximately 12:56 PM[.] 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 § 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 § 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 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 photographic identification containing the purchaser's date of birth, that no cigarette purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Here, Respondent had six violations of regulations found at 21 C.F.R. pt. 1140 within a thirty-six month period. I found Respondent to have committed four violations of the regulations found at 21 C.F.R. pt. 1140 in a previous civil money penalty action. *Satsang, Inc.*, DAB CR2997 at 3. Most recently, on February 15, 2014, Respondent sold cigarettes to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). During that same transaction, Respondent failed to verify, by means of photographic identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older, in violation of 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. 21 C.F.R. §§ 17.2, 17.11(a)(2). Therefore, I find that a civil money penalty of \$5,000 is warranted and so order one imposed. Pursuant to 21 C.F.R. § 17.11 (b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Steven T. Kessel
Administrative Law Judge