

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Shivam, LLC
d/b/a Shivam Variety

Respondent.

Docket No. C-13-921
FDA Docket No. FDA-2013-H-0750

Decision No. CR2887

Date: August 13, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Shivam, LLC d/b/a Shivam Variety (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 assess a civil money penalty of \$500.

CTP began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that on two separate occasions, Respondent unlawfully sold a tobacco product to a minor and failed to verify that the purchaser of the tobacco product was of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301 – 399d,

and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$500 for these violations.

On June 25, 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 must take one of the following three actions: pay the penalty; file an answer; or request an extension of time within which to file an answer. CTP further stated that if Respondent does not comply with one of the actions within 30 days, an Administrative Law Judge (ALJ) 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 or timely 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 by default and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Shivam Variety, an establishment that sells tobacco products and is located at 521 Main Street, Brockton, Massachusetts 02301. Complaint ¶ 3.
- On March 26, 2011, an FDA-commissioned inspector observed two violations at Shivam Variety. First, “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 11:10 AM.” The inspector also noted that “the minor’s identification was not verified before the [March 26, 2011] sale . . .” Complaint ¶ 10.
- On May 5, 2011, CTP issued a Warning Letter to Shivam Variety. The letter informed Respondent of the violations the FDA-commissioned inspector observed on March 26, 2011, and explained that the FDA could initiate a civil money penalty or other regulatory action if Respondent failed to correct the violations. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of violations and that Respondent was responsible for complying with the law. Complaint ¶ 10.
- On June 30, 2011, on behalf of Respondent Jay Patel responded to the Warning Letter in an undated letter and telephone call. In his correspondence, Mr. Petal “apologized for the sale to the minor.” He

further stated that, “[E]mployees were told about the Warning Letter and instructed to check ID for all persons under age 40 who wish to purchase tobacco products.” Complaint ¶ 11.

- On November 2, 2011, CTP responded to Mr. Patel by letter, acknowledging receipt of the establishment’s response. Mr. Patel was also reminded of Shivam Variety’s “continuing obligation to be in compliance with the Act and its implementing regulations.” Complaint ¶ 11.
- During a two-part inspection on November 3 and 5, 2012, FDA-commissioned inspectors documented two additional violations. First, “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on November 3, 2012, at approximately 12:06 PM.” The inspector also noted that, “the minor’s identification was not verified before the sale.” Complaint ¶ 1.
- On November 12, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on November 3, 2012, and that during the inspection a minor entered the establishment and purchased a regulated tobacco product. The Notice also warned the Respondent that other potential violations of the federal tobacco law may have been observed and if CTP determined that there were additional violations of federal law, the establishment may receive further notification from the FDA. Complaint ¶ 2.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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 section 906(d) of the Act, codified at 21 U.S.C. § 387f(d); 21 U.S.C. § 387(a)(7)(B); 21 C.F.R. § 1140.1(b). 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 the purchaser’s date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

In the present case, on two separate occasions, Respondent violated 21 C.F.R. § 1140.14(a); 21 C.F.R. § 1140.14(b)(1). First, on March 26, 2011, Respondent unlawfully sold a tobacco product to a minor and failed to verify, by means of photo identification, the person purchasing the tobacco product was 18 years of age or older. Subsequently, on November 3, 2012, Respondent again unlawfully sold a tobacco product to a minor and failed to verify the person purchasing tobacco was of lawful age. Therefore, Respondent’s actions on two separate

occasions, occurring on March 26, 2011 and November 3, 2012, at the same establishment constitute violations of law for which a civil money penalty is warranted.

The regulations require the ALJ to impose a civil money penalty that is either the maximum amount provided for by law for the violations alleged; or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1).

Respondent received a Warning Letter after the first violation and subsequently committed two additional violations within a 24-month period. The regulations provide that the maximum penalty for this action is \$500. 21 C.F.R. § 17.2. In its Complaint, CTP seeks a civil money penalty in the amount of \$500. Because Respondent failed to file a timely Answer or request an extension of time to file an Answer, I impose a civil money penalty in the amount of \$500.

/s/

Steven T. Kessel
Administrative Law Judge