

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Pure Foods, Inc.
d/b/a 7-Eleven #15036,

Respondent.

Docket No. C-13-1198
FDA Docket No. FDA-2013-H-0986

Decision No. CR2979

Date: November 1, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Pure Foods, Inc. d/b/a 7-Eleven #15036 (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 initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent unlawfully sold tobacco products to a minor and failed to verify that a purchaser of a 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 August 27, 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 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 explained that if Respondent did not comply with one of the actions within 30 days, an Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has neither filed an Answer within the time provided by regulation, nor 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 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 7-Eleven #15036, an establishment that sells tobacco products and is located at 309 Smallwood Drive, Waldorf, Maryland 20602. Complaint ¶ 3.
- On October 10, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at 7-Eleven #15036. Specifically, the inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 2:26 PM ET. Complaint ¶ 10.
- On October 15, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) to Respondent’s establishment informing Respondent that an inspection had been conducted on October 10, 2012, and “that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 2:26 PM.” Complaint ¶ 10.
- On November 29, 2012, CTP issued a Warning Letter to Respondent specifying the violation that the inspector observed on October 10, 2012. The letter warned Respondent that if it failed to correct the violation, civil money penalties could be imposed on it or other regulatory action by the FDA. CTP further explained that the letter was not intended to provide an

exhaustive list of violations and that Respondent was responsible for complying with the law. Complaint ¶ 10.

- “On December 2, 2012, by letter, Suri Sarabjit, who identified himself as the supervisor of the establishment, responded to the Warning Letter” on Respondent’s behalf. In its Complaint, CTP summarized Mr. Sarabjit’s response as follows: “Mr. Sarabjit stated that the employee responsible for the sale . . . was warned that further violations would result in suspension or termination. Mr. Sarabjit further stated that all employees are trained via video at least yearly about proper identification procedures and that the establishment has mock customers come in to randomly check to ensure employees are properly checking identification.” Complaint ¶ 11.
- On February 12, 2013, by letter, CTP responded to Mr. Sarabjit “acknowledging receipt of his response and reminding [Respondent] of its continuing obligation to be in compliance with Act and its implementing regulations.” Complaint ¶ 11.
- During a subsequent inspection, conducted on February 20, 2013, and February 28, 2013, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Maverick cigarettes on February 20, 2013, at approximately 2:38 PM ET;” and that “the minor’s identification was not verified before the sale . . . on February 20, 2013, at approximately 2:38 PM ET.” Complaint ¶ 1.
- On February 25, 2013, CTP issued a Notice of Compliance Check Inspection (Notice) to Respondent’s establishment informing Respondent that an inspection had been conducted on February 20, 2013, and “that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 2:38 PM.” Complaint ¶ 2.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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). *See* 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 purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

In the present case, Respondent committed three violations of 21 C.F.R. Part 1140 within a four-month period. Specifically, on October 10, 2012, and during a subsequent inspection, on February 20, 2013, Respondent unlawfully sold a regulated tobacco product to a minor. 21 C.F.R. § 1140.14(a). Additionally, on February 20, 2013, Respondent failed to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth. 21 C.F.R. § 1140.14(b)(1). Respondent's actions and omissions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty that is either the maximum amount provided for by law, or the amount sought in the Complaint, whichever amount is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The maximum penalty for three violations in a four-month period is \$500. *See* 21 C.F.R. § 17.2. In its Complaint, CTP seeks a civil money penalty in the amount of \$500. Accordingly, I find that a civil money penalty in the amount of \$500 is permissible and order it imposed.

/s/
Steven T. Kessel
Administrative Law Judge