

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

BSKRAZA, LLC
d/b/a Select Food Mart,

Respondent.

Docket No. C-13-1053
FDA Docket No. FDA-2013-H-0867

Decision No. CR2946

Date: October 7, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against BSKRAZA, LLC d/b/a Select Food Mart (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 on two separate occasions Respondent unlawfully sold a tobacco

product 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 15, 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 Select Food Mart, an establishment that sells tobacco products and is located at 125 New Britain Avenue, Hartford, Connecticut 06106. Complaint ¶ 3.
- On July 10, 2012, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Select Food Mart. 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 2:56 PM ET” The inspector observed an additional violation of 21 C.F.R. Part 1140 when “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- Additionally, on July 20, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on July 10, 2012, and “that during the inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 2:56 PM.” The Notice also warned Respondent “that other

potential violations of the federal tobacco law may have been observed,” and if “CTP determined that there was a violation of federal law, the establishment may receive further notification from [the] FDA.” Complaint ¶ 10.

- “[O]n September 20, 2012, CTP issued a Warning Letter to Select Food Mart.” The letter informed Respondent of the violations the FDA-commissioned inspector observed at the establishment on July 10, 2012, and warned Respondent “that failure to correct the violations may result in a civil money penalty action, or other regulatory action by [the] FDA.” CTP further 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.
- Respondent did not reply to the Warning Letter. However, UPS records confirmed that on September 21, 2012, the Warning Letter was accepted by “Harris.” Complaint ¶ 11.
- On January 4, 2013, FDA-commissioned inspectors documented two additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. Specifically, the inspectors documented a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Maverick cigarettes . . . at approximately 11:07 AM ET.” The inspector documented an additional violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale” Complaint ¶ 1.
- On January 8, 2013, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on January 4, 2013, and “that during the inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 11:07 AM.” The Notice warned Respondent “that other potential violations of the federal tobacco law may have been observed,” and if “CTP determined that there was a violation of federal law, the establishment may receive further notification from [the] FDA.” 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.

