

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Habibco BP Inc.
d/b/a BP,

Respondent.

Docket No. C-13-993
FDA Docket No. FDA-2013-H-0819

Decision No. CR2916

Date: August 30, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Habibco BP Inc. d/b/a BP (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 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 Respondent unlawfully sold a tobacco product to a minor on two separate occasions 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 July 12, 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 may 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 BP, an establishment that sells tobacco products and is located at 9290 East 131st Street, Fishers, Indiana 46038. Complaint ¶ 3.
- On August 14, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at BP. The inspector observed that “a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes . . . at approximately 3:02 PM.” Complaint ¶ 10.
- “[O]n October 25, 2012, CTP issued a Warning Letter to BP.” The letter informed Respondent of the violation the FDA-commissioned inspector observed at the establishment on August 14, 2012, and explained that Respondent’s failure to correct the violation “may result in a civil money penalty . . . 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.
- “On November 1, 2012[,] by letter, Mike Isifian, the General Manager of the Habibco BP Station, responded to the Warning Letter on behalf of Respondent.” In his response, Mr. Isifian stated that “[E]mployees go through an extensive training process and they are trained both to request identification from anyone who appears to be younger than 30 years of age

and to check for proper forms of identification.” By letter, dated December 28, 2012, CTP responded to Mr. Isifian acknowledging receipt of his response. Complaint ¶ 11.

- On January 20, 2013, FDA-commissioned inspectors observed two additional violations at Respondent’s establishment. First, “a person younger than 18 years of age was able to purchase a package of Grizzly Premium Wintergreen Long Cut smokeless tobacco . . . at approximately 12:16 PM ET.” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 1.
- On January 25, 2013, CTP issued a Notice of Compliance Check Inspection (Notice) informing Respondent that an inspection had been conducted on January 20, 2013, and “that during the inspection a minor was able to enter the establishment and purchase a regulated tobacco product” The Notice also warned 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 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 violated 21 C.F.R. Part 1140 on three occasions within a 24-month period. First, on August 14, 2012, Respondent unlawfully sold a regulated tobacco product to a minor. Subsequently, on January 20, 2013, Respondent again sold a regulated tobacco product to a minor and failed to verify, by means of photo identification, that the purchaser was 18 years of age or older. Therefore, Respondent’s actions on three separate occasions constitute violations of law for which a civil money penalty is warranted.

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); 21 C.F.R. § 17.11(a)(2). After the first violation, Respondent received a Warning Letter, 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