

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

B Plus B Enterprise, LLP
d/b/a B Mart / Citgo,

Respondent.

Docket No. C-13-1223
FDA Docket No. FDA-2013-H-1014

Decision No. CR2973

Date: October 30, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, B Plus B Enterprise, LLP d/b/a B Mart / Citgo, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$250.

CTP began this case by serving the 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, failed to verify that the tobacco purchaser was of sufficient age prior to this transaction, and impermissibly utilized a self-service display of regulated tobacco products in a non-exempt facility, thereby violating

the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On August 29, 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 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 timely take one of these actions the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty, and the Respondent fails to timely answer or request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here. I conclude that it is based on the allegations of the Complaint and Respondent's failure to answer them.

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 B Mart / Citgo, an establishment that sells tobacco products and is located at 592 Providence Road, Brooklyn, Connecticut 06234. Complaint ¶ 2.
- On September 21, 2012, an FDA-commissioned inspector observed violations of the regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff "[sold] tobacco products to a minor[;] . . . [s]pecifically, a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . at approximately 10:50 AM . . ." Respondent's staff also violated 21 C.F.R. § 1140.14(b)(1) when the staff "[f]ail[ed] to verify the age of a person purchasing tobacco products[,] by means of photographic identification containing the bearer's date of birth[,] . . . before the sale . . . on September 21, 2012 . . ." Complaint ¶ 9.
- On November 15, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from September 21, 2012. In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if it failed to correct the violations. The letter

also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 9.

- On November 21, 2012, Muwahad Abel responded in writing to the Warning Letter on behalf of Respondent. "Mr. Abel stated that the violation was discussed with his employees and [that] all employees were instructed to verify the identification of any person under the age of twenty-seven." Complaint ¶ 10.
- On February 28, 2013, and March 13, 2013, FDA-commissioned inspectors documented an additional violation of 21 C.F.R. Part 1140 during a two-part inspection of Respondent's establishment. Respondent violated 21 C.F.R. § 1140.16(c) by "using a self-service display in a non-exempt facility." The inspectors documented that the establishment "ha[d] tobacco products, including chewing tobacco[,] accessible to the public." On those dates, the inspectors noted that Respondent's establishment operated as a convenience store and gas station. 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 section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no purchaser of cigarettes is younger than 18 years of age. Under 21 C.F.R. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. The regulations prohibit retailers from using self-service displays to sell cigarettes and smokeless tobacco. 21 C.F.R. § 1140.16(c). However, self-service displays are permitted if located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. 21 C.F.R. § 1140.16(c)(2)(ii).

Here, Respondent violated 21 C.F.R. § 1140.14(a) on September 21, 2012, when its staff sold cigarettes to a minor. On that same date, Respondent also violated 21 C.F.R. § 1140.14(b)(1) when its staff did not verify, by checking the tobacco purchaser's photographic identification, that the tobacco purchaser was 18 years of age or older prior to this transaction. Additionally, on February 28, 2013, and March 13, 2013, Respondent's establishment contained a self-service display of tobacco products, including smokeless tobacco. On those dates, the establishment operated as a convenience store and gas station that was open to the public. Therefore, Respondent impermissibly utilized a self-service display for regulated

