

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-2312)

Complainant

v.

QM Enterprises, Inc.
d/b/a BP,

Respondent.

Docket No. C-15-800

Decision No. CR3687

Date: March 6, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, QM Enterprises, Inc. d/b/a BP, at 714 East Warren Avenue, Detroit, Michigan 48201, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that BP impermissibly sold cigarettes to a minor and failed to verify, by means of photo identification containing a date of birth, that a cigarette purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent BP previously admitted to two violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$2,000 civil money penalty against Respondent BP.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 12, 2015, CTP served the complaint on Respondent BP by United Parcel Service. 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 in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent BP has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to Respondent BP on March 14, 2013, citing violations¹ of 21 C.F.R. pt. 1140 on February 24, 2013, at Respondent's business establishment, 714 East Warren Avenue, Detroit, Michigan 48201;
- On February 4, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-565, FDA Docket Number FDA-2014-H-0097, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. CTP alleged those violations to have occurred on February 24, 2013, and July 20, 2013;
- The previous action concluded when Arfat Ali, Respondent's authorized representative, settled the claims on Respondent's behalf. On February 18, 2014, Mr. Ali signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on April 15, 2014;
- At approximately 6:14 p.m. on June 6, 2014, at Respondent's business establishment, 714 East Warren Avenue, Detroit, Michigan 48201, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age.

¹ In the complaint, CTP describes the action or actions that took place at Respondent BP's business establishment on February 24, 2013, as both "a violation" and as "violations." Complaint ¶ 10. In a previous administrative complaint issued on February 5, 2014, and attached to the present complaint, CTP described two discrete violations at Respondent BP's business establishment on February 24, 2013: a violation of 21 C.F.R. § 1140.14(a) and a violation of 21 C.F.R. § 1140.14(b)(1). Therefore, I will infer that CTP's description in the present complaint of "a violation" occurring on February 24, 2013, was a typographical error.

