

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-0951)

Complainant

v.

Yohana, Inc.
d/b/a 7-Eleven 23696,

Respondent.

Docket No. C-14-1442

Decision No. CR3361

Date: September 9, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Yohana, Inc. d/b/a 7-Eleven 23696, at 650 East University Boulevard, Silver Spring, Maryland 20901, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that 7-Eleven 23696 unlawfully sold cigarettes to a minor, 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. An Administrative Law Judge (ALJ) has previously found Respondent to have committed two violations of regulations found at 21 C.F.R. pt. 1140. *Yohana, Inc. d/b/a 7-Eleven #23696*, DAB CR2947, at 2-3 (2013); Complaint ¶ 11. Therefore, CTP seeks to impose a \$500 civil money penalty against Respondent 7-Eleven 23696.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 11, 2014, CTP served the complaint on Respondent 7-Eleven 23696 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 ALJ 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 7-Eleven 23696 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 7-Eleven 23696 on October 25, 2012, citing a violation of 21 C.F.R. pt. 1140 on August 6, 2012, at Respondent's business establishment, 650 East University Boulevard, Silver Spring, Maryland 20901;
- On August 14, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1101, FDA Docket Number FDA-2013-H-0907, against Respondent for two violations of 21 C.F.R. pt. 1140 within a twelve-month period. CTP alleged those violations to have occurred on August 6, 2012, and January 10, 2013;
- The previous action concluded when the ALJ issued an Initial Decision and Default Judgment in which he found that Respondent 7-Eleven 23696 committed two violations of 21 C.F.R. pt. 1140 by selling cigarettes to a minor on two separate occasions. *Yohana, Inc. d/b/a 7-Eleven #23696*, DAB CR2947, at 2-3 (2013); Complaint ¶ 11;
- At approximately 11:54 AM on December 17, 2013, at Respondent's business establishment, 650 East University Boulevard, Silver Spring, Maryland 20901, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

These facts establish Respondent 7-Eleven 23696's liability 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. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age.

