

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

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

Respondent.

Docket No. C-13-1101
FDA Docket No. FDA-2013-H-0907

Decision No. CR2947

Date: October 16, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Yohana, Inc. d/b/a 7-Eleven #23696, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not 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 \$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 impermissibly sold cigarettes to a minor on two occasions, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$250.

On August 15, 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 proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns 7-Eleven #23696, an establishment that sells tobacco products and is located at 650 East University Boulevard, Silver Spring, Maryland 20901. Complaint ¶ 3.
- On August 6, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed 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 Newport Box cigarettes . . . at approximately 11:05 AM ET.” Complaint ¶ 10.
- CTP issued a Notice of Compliance Check Inspection to 7-Eleven #23696 on August 13, 2012, due to the inspection on August 6, 2012. The Notice of Compliance Check Inspection specifically notified Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 11:05 AM” on August 6, 2012. Complaint ¶ 10.
- On October 25, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from August 6, 2012. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The

Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.

- Stephen Chege, Field Consultant to 7-Eleven, Inc., responded to the Warning Letter on November 2, 2012, by email. “Mr. Chege stated that, among other things, all employees will be required to retake 7-Eleven's training videos on tobacco sales and that all employees have been reminded that they must card any person under the age of 27, and if they are not sure of the customer's age they must card everyone who attempts to purchase.” Complaint ¶ 11.
- On January 10, 2013, at approximately 12:12 PM ET, FDA-commissioned inspectors documented an additional violation of 21 C.F.R. Part 1140 at Respondent’s establishment. 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 Newport Box cigarettes” Complaint ¶ 1.
- On January 14, 2013, CTP issued a Notice of Compliance Check Inspection to 7-Eleven #23696 as a result of the inspection on January 10, 2013. The Notice of Compliance Check Inspection specifically notified Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 12:12 PM” on January 10, 2013. The Notice stated that the violation described was not necessarily the only violation reported. Complaint ¶ 2.

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 distributed or offered for sale in any state 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). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

Taking the above alleged facts as true, Respondent had two violations of a regulation contained in 21 C.F.R. Part 1140 within a six-month period. Specifically, Respondent had a violation on August 6, 2012, and a violation on January 10, 2013. Respondent’s actions twice violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

