

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Three J Food Market Inc.,

Respondent.

Docket No. C-13-1122

FDA Docket No. FDA-2013-H-0923

Decision No. CR2954

Date: October 18, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Three J Food Market Inc., that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

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 minors and failed to verify that cigarette purchasers were 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, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$500.

On August 21, 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 Three J Food Market, an establishment that sells tobacco products and is located at 2659 South 66th Street, Philadelphia, Pennsylvania 19142. Complaint ¶ 3.
- On August 23, 2012, an FDA-commissioned inspector observed two violations 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 Maverick Box 100s cigarettes . . . at approximately 1:26 PM[.]” The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor's identification was not verified before the sale” Complaint ¶ 10.
- CTP issued a Notice of Compliance Check Inspection to Three J Food Market on August 31, 2012, “stating that an inspection had been conducted on August 23, 2012, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 1:26 PM.” The Notice stated that the violation described was not necessarily the only violation reported. Complaint ¶ 10.
- CTP issued a Warning Letter to Respondent on November 8, 2012, regarding the inspector’s observations from August 23, 2012. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 1140.14(b)(1), and that the named violations were 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 violations, 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.

- “Three J Food Market Inc. Management” responded to the Warning Letter on Respondent’s behalf with an unsigned November 12, 2012 letter. The letter “stated that the establishment has taken precautions to avoid future violations and will check identification for any individual attempting to purchase tobacco products.” Complaint ¶ 11.
- On February 7, 2013, at approximately 4:20 PM ET, FDA-commissioned inspectors documented two additional violations 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 100s cigarettes . . . [.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor's identification was not verified before the sale” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Three J Food Market on February 12, 2013, “stating that an inspection had been conducted on February 7, 2013, and that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 4:20 PM.” 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). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a six-month period. Specifically, Respondent had two violations on August 23, 2012, and two violations on February 7, 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). Respondent’s actions also twice violated the requirement

