Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

FFJ, Inc. d/b/a Dellwood Market,

Respondent.

Docket No. C-13-719 FDA Docket No. FDA-2013-H-0517

Decision No. CR2832

Date: June 18, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint (Complaint) against Respondent, FFJ, Inc. d/b/a Dellwood Market, that alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 assess a civil money penalty of \$500.

CTP began this case by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that Respondent unlawfully sold tobacco products to minors and failed to verify that the purchasers of tobacco products were of sufficient age on two separate occasions, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301-399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil monetary penalty of \$500 for these violations.

On May 6, 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 take one of these actions within 30 days, an Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to "assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act]," issue a default judgment and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Dellwood Market, an establishment that sells tobacco products and is located at 1620 Chambers Road, Saint Louis, Missouri 63136. Complaint ¶ 3.
- On June 28, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) for "[s]elling tobacco products to a minor" and a violation of 21 C.F.R. § 1140.14(b)(1) for "[f]ailing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth[.]" Complaint ¶ 10.
- CTP issued a Notice of Compliance Check Inspection on July 6, 2012, informing Respondent that an inspection had been performed on June 28, 2012, at approximately 6:52 PM and that violations had been noted. Complaint ¶ 10.
- "[O]n September 6, 2012, CTP issued a Warning Letter to Dellwood Market." Complaint ¶ 10. The letter cited the violations the FDAcommissioned inspector had observed on June 28, 2012, and explained that Respondent could face a civil money penalty or other regulatory action if it failed to correct the violations. Complaint ¶ 10. Moreover, CTP explained that the Warning Letter was not intended to provide an exhaustive list of

violations and that Dellwood Market was responsible for complying with the law. Complaint \P 10.

- United Parcel Service delivered the Warning Letter on September 7, 2012, to "Musleh." Complaint ¶ 11. CTP, however, did not receive any response to the Warning Letter. Complaint ¶ 11.
- During a subsequent inspection, FDA-commissioned inspectors documented two additional violations. Complaint ¶ 1. "Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on January 14, 2013, at approximately 4:35 PM CT." Complaint ¶ 1. Also, "the minor's identification was not verified before the [January 14, 2013,] sale...." Complaint ¶ 1.
- CTP informed Respondent on January 17, 2013, of the January 14, 2013, inspection and documented violations through a Notice of Compliance Check Inspection. Complaint ¶ 2. The Notice warned "that other potential violations of federal tobacco law may have been observed," and, if violations had occurred, FDA could notify Respondent further. Complaint ¶ 2.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R § 1140.1(b). Those regulations prohibit the sale of "cigarettes or smokeless tobacco to any person younger than 18 years of age[.]" 21 C.F.R. § 1140.14(a). Those regulations also require a retailer to "verify by means of photographic identification containing the bearer's date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]" 21 C.F.R. § 1140.14(b)(1).

Here, Respondent violated both 21 C.F.R. § 1140.14(a) and (b)(1). First, on June 28, 2012, Respondent unlawfully sold cigarettes to a minor and failed to verify that the purchaser was of sufficient age. Then, most recently, on January 14, 2013, Respondent again unlawfully sold cigarettes to a minor without verifying the purchaser's age. Therefore, Respondent's actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

The regulations require me to impose a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed a fourth

violation within a 24-month period, the maximum penalty for which is \$2000. 21 C.F.R. § 17.2. CTP, however, requested a civil money penalty in the amount of \$500. 21 C.F.R. § 17.2. Therefore, I impose a civil money penalty in the amount of \$500.

/s/ Steven T. Kessel Administrative Law Judge