

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Smith's Food & Drug Centers Inc.
d/b/a Fry's Marketplace,

Respondent.

Docket No. C-13-116
FDA Docket No. FDA-2012-H-1142

Decision No. CR2678

Date: December 27, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Smith's Food & Drug Centers Inc. d/b/a Fry's Marketplace, that alleges facts and legal authority sufficient to justify the imposition of 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 serving a 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 tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser through photographic identification on one occasion, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing

regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$500 for these three violations.

On November 21, 2012, 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, the 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 money penalty. Accordingly, I must determine whether the allegations in the complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Fry’s Marketplace, an establishment that sells tobacco products and is located at 985 East Riggs Road, Chandler, Arizona 85249.
- On March 8, 2012, at Fry’s Marketplace, an FDA-commissioned inspector observed the “sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a).” Complaint ¶ 9.
- “[O]n April 5, 2012, CTP issued a Warning Letter to Fry’s Marketplace.” Complaint ¶ 9. The letter informed Respondent of the violation that the FDA-commissioned inspector had observed on March 8, 2012, and that the warning was not intended to provide an exhaustive list of violations. Moreover, the letter informed Respondent that Fry’s Marketplace maintained the responsibility to ensure compliance with the law and that the failure to correct violations could result in the imposition of a civil money penalty or other regulatory action.
- On April 23, 2012, CTP received written correspondence on behalf of Respondent. According to CTP, Respondent advised “that all associates who operate a register are currently taking a tobacco training course to prevent selling tobacco products to minors.” Complaint ¶ 10.

- On May 18, 2012, CTP acknowledged in writing that it had received Respondent's correspondence and reminded Respondent that it had a continuing duty to comply with the Act and implementing regulations.
- Pursuant to a two-part inspection conducted on June 15 and 22, 2012, FDA-commissioned inspectors noted that "a person younger than 18 years of age was able to purchase a package of Marlboro Black cigarettes on June 15, 2012, at approximately 11:21 AM[,]" in violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 1.a. Additionally, the inspectors noted a violation of 21 C.F.R. § 1140.14(b)(1) because "the minor's identification was not verified before the [June 15, 2012] sale[.]" Complaint ¶ 1.b.

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). The 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). The regulations also require a retailer to "verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age[,]" 21 C.F.R. § 1140.14(b)(1), though "[n]o such verification is required for any person over the age of 26[,]" 21 C.F.R. § 1140.14(b)(2).

Here, Respondent sold tobacco products to a minor on two separate occasions and failed to verify the age of the purchaser on one of those occasions in violation of the foregoing regulations. Respondent's actions and omission constitute violations of law for which a civil money penalty is merited. The regulations require the imposition of 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)(1)-(2). Respondent has committed three violations within a 24-month period, the maximum penalty for which is \$500. 21 C.F.R. § 17.2; *Guidance for FDA and Tobacco Retailers, Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (Revised)*, November 2012, (available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>). CTP, through its Complaint, requested

