

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 Food & Drug #23,

Respondent.

Docket No. C-13-316
FDA Docket No. FDA-2013-H-0087

Decision No. CR2719

Date: March 12, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Smith's Food & Drug Centers, Inc. d/b/a Fry's Food & Drug #23, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$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 and repeatedly sold tobacco products to a minor, 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 January 28, 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 timely 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 Fry’s Food & Drug #23, an establishment that sells tobacco products and is located at 5941 East McKellips Road, Mesa, AZ. Complaint ¶ 3.
- On January 19, 2012, an FDA-commissioned inspector observed Respondent violating 21 C.F.R. § 1140.14(a), a regulation prohibiting the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age, at the establishment. Complaint ¶ 10.
- On February 16, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 19, 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 failure to correct the violation could result in the imposition of a civil money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. *Id.*

- FDA received a response to its Warning Letter on February 29, 2012, from Tina Crean on behalf of Respondent. Ms. Crean “stated that all associates who operate a register re-signed the company's tobacco policy.” Complaint ¶ 11.
- On November 2, 2012, CTP issued a Notice of Compliance Check Inspection to Respondent’s establishment due to a minor’s purchase of a package of Pall Mall Blue 100's cigarettes on October 30, 2012 at approximated 10:13 AM Arizona time. The Notice stated that the violation described was not necessarily the only violation reported and that FDA may further contact the establishment. Complaint ¶¶ 1-2.

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 or smokeless tobacco 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 regulations contained in 21 C.F.R. Part 1140 within a ten month period. Specifically, Respondent had a violation on January 19, 2012, and a violation on October 30, 2012. Respondent’s actions violated regulations prohibiting the sale of cigarettes or smokeless tobacco to any person 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.

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). The regulations currently allow a maximum penalty of \$250 for two violations within a 10 month period, 21 C.F.R. § 17.2, and CTP has requested a fine of that amount. Complaint ¶ 1. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge