

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

SMR Petroleum
d/b/a South Street Market,

Respondent.

Docket No. C-13-1088
FDA Docket No. FDA-2013-H-0893

Decision No. CR2940

Date: October 3, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, SMR Petroleum d/b/a South Street Market, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500. 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 order that Respondent pay a civil money penalty in the amount 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's staff unlawfully sold regulated tobacco products to minors on two separate occasions and failed to

verify that the tobacco purchasers were of sufficient age prior to these transactions, 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.

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 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 by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty, and the respondent fails to answer timely or to request an extension. *See* 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here. I conclude that it is based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. *See* 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns South Street Market, an establishment that sells tobacco products and is located at 80 South Street, Danbury, Connecticut 06810. Complaint ¶ 3.
- On July 2, 2012, an FDA-commissioned inspector observed violations of 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff "[sold] tobacco products to a minor[;] . . . [s]pecifically, a person younger than 18 years of age was able to purchase a package of Natural American Spirit cigarettes . . . at approximately 11:30 AM ET" Respondent's staff also violated 21 C.F.R. § 1140.14(b)(1) when the staff "[f]ail[ed] to verify the age of a person purchasing tobacco products[,] by means of photographic identification containing the bearer's date of birth[,] . . . before the sale . . . [on] July 2, 2012" Complaint ¶ 10.
- On September 13, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from July 2, 2012. In addition to describing the violations, the letter advised Respondent that the FDA may

initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.

- On December 21, 2012, Avitar Singh, an officer of SMR Petroleum, responded in writing to the Warning Letter on behalf of Respondent. “[Mr.]Singh stated that employees [could] access a newly incorporated checklist for tobacco product sales, and that rules and regulations for tobacco sales, including the requirement to check a photographic identification card, would be reviewed with each employee at the establishment.” Complaint ¶ 11.
- On January 30, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. Specifically, at approximately 9:49 AM, Respondent's staff sold a package of Newport Box cigarettes to a person younger than 18 years of age. In addition, Respondent's staff did not verify the tobacco purchaser's age by checking the minor's photo identification prior to this sale. Complaint ¶ 1.

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 sold or distributed 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age.

Here, Respondent's staff sold cigarettes to minors in violation of 21 C.F.R. § 1140.14(a), on two separate occasions: July 2, 2012, and January 30, 2013. Prior to these transactions, Respondent's staff did not verify, by checking the tobacco purchaser's photographic identification, that the tobacco purchaser was 18 years of age or older as required by 21 C.F.R. § 1140.14(b)(1). 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. Accordingly, I find that a civil money penalty of \$500 is permissible under 21 C.F.R. § 17.2 and order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge