

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1419)

Complainant,

v.

Seetaram LLC / Daya Singh
d/b/a Twin Stop,

Respondent.

Docket No. C-14-1937

Decision No. CR3445

Date: November 6, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Seetaram LLC / Daya Singh d/b/a Twin Stop, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$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 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. pt. 1140 (2013). CTP seeks a civil money penalty of \$250.

On September 24, 2014, 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 Twin Stop, an establishment that sells tobacco products located at 2 Grove Street, Putnam, Connecticut 06260. Complaint ¶ 2.
- During an inspection of Respondent’s establishment on October 29, 2013, an FDA-commissioned inspector observed “multiple customer-accessible shelves and unlocked display cabinets containing cigarette tobacco and smokeless tobacco throughout the sales floor. The establishment was open to the general public during business hours.” Complaint ¶ 9.
- On January 2, 2014, CTP issued a Warning Letter informing Respondent of the inspector’s October 29, 2013 observation. The letter explained that the observation constituted a violation of regulations found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action. Complaint ¶ 9.
- Based on UPS records, the Warning Letter was received by “Gaw” on January 4, 2014. Complaint ¶ 9.
- During a subsequent two-part inspection of Respondent’s establishment conducted on March 14 and 25, 2014, FDA-commissioned inspectors documented the use of a self-service display in a non-exempt facility. Specifically, on March 14, 2014, “a person younger than 18 years of age was able to access cigarette tobacco from one of these displays. The facility is open to the general public during business hours.” Complaint ¶ 1.

These facts establish Respondent Seetaram LLC / Daya Singh d/b/a Twin Stop's liability 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). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(c) a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine or a self-service display). Also, under 21 C.F.R. § 1140.16(c), self-service displays of cigarettes and smokeless tobacco are a prohibited method of sale, except where no minors are present or permitted to enter the establishment at any time. 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent impermissibly used a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c) on October 29, 2013 and March 14, 2014. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge