

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Kulwinder Kaur
d/b/a 7-Eleven #19092,

Respondent.

Docket No. C-13-155
FDA Docket No. FDA-2012-H-1177

Decision No. CR2696

Date: January 23, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Kulwinder Kaur d/b/a 7-Eleven #19092, alleging facts and legal authority sufficient to justify the imposition of 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 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 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 \$500.

On December 12, 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 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 complaint 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 7-Eleven #19092, an establishment that sells tobacco products and is located at 3501 West Bethany Home Road, Phoenix, AZ 85019. Complaint ¶ 3.
- On November 8, 2011, an FDA-commissioned inspector observed a violation of 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 Respondent’s establishment. Complaint ¶ 12.
- On January 19, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from November 8, 2011. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), that this regulation prohibits the sale of tobacco products to individuals under the age of 18, 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.*
- Kulwinder “Kelly” Kaur contacted CTP by telephone on February 14, 2012, on Respondent’s behalf. Ms. Kaur described herself as the owner of

7-Eleven #19092 and “stated that it is 7-Eleven's policy to card everyone under 27 years of age and to not sell tobacco products to anyone under 18.” She further stated that she would remind staff of this policy. Complaint ¶ 13.

- CTP responded to Ms. Kaur with a letter dated February 21, 2012, in which it acknowledged receiving Ms. Kaur’s phone call and reminded her of 7-Eleven, Inc. d/b/a 7-Eleven #19092’s continued obligation to comply with the Act and its implementing regulations. *Id.*
- On March 29, 2012, an inspection documented another violation by Respondent of 21 C.F.R. § 1140.14(a), when Respondent sold “a package of Newport Box cigarettes” to a person younger than 18 years of age at approximately 10:38 AM. Complaint ¶ 10.
- CTP initiated a civil money penalty action on August 7, 2012, against Respondent as a result of the March 29, 2012 violation. The action “concluded with Kulwinder Kaur, d/b/a 7-Eleven #19092 paying the penalty and the court closing the case on October 1, 2012.” 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 regulated tobacco product, “a package of Natural American Spirit cigarettes,” at the establishment on October 25, 2012, at approximately 12:06 PM. The Notice stated that the violation described was not necessarily the only violation reported. Complaint ¶ 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 three violations of regulations contained in 21 C.F.R. Part 1140 within a twelve month period. Specifically, Respondent had a violation on November 8, 2011, a violation on March 29, 2012, and a violation on October 25, 2012. Respondent’s actions on each occasion violated the prohibition on retailers’ sales of cigarettes or smokeless

tobacco to individuals less 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). Accordingly, I find that a civil money penalty of \$500 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge