

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Yong Hyun Kim
d/b/a Minute Stop Market,

Respondent.

Docket No. C-13-579
FDA Docket No. FDA-2013-H-0357

Decision No. CR2802

Date: May 29, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Yong Hyun Kim d/b/a Minute Stop Market, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. 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 \$2,000.

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 Yong Hyun Kim d/b/a Minute Stop Market impermissibly sold tobacco products to minors and failed to verify that a purchaser of cigarettes was 18 years of age or older, 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 \$2,000.

On March 29, 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 Minute Stop Market, an establishment that sells tobacco products and is located at 3373 Jackson Highway, Chehalis, WA 98532. Complaint ¶ 2.
- On February 17, 2011, at an undisclosed time, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) at Respondent’s establishment. Section 1140.14(a) prohibits the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. Complaint ¶ 9.
- On April 14, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 17, 2011. The letter explained that the act the inspector observed violated 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. Complaint ¶ 9.

- Yong Hyun Kim responded to the Warning letter by telephone and stated that “employees would be required to verify the age of any purchaser of tobacco products.” Complaint ¶ 10.
- An FDA-commissioned inspector or inspectors documented an additional violation at the Minute Stop Market during an inspection conducted on October 25, 2011, and November 7, 2011, at an undisclosed time or times. The inspector or inspectors observed a violation of 21 C.F.R. § 1140.14(a), “for selling tobacco products to a minor.” Complaint ¶ 11.
- CTP brought a civil money penalty action against Yong Hyun Kim d/b/a Minute Stop Market on January 5, 2012, docket number FDA-2012-H-0016, for a violation of Part 1140. Complaint ¶ 11.
- An Administrative Law Judge issued an Order for Default Judgment in the civil money penalty action on February 16, 2012. Before the Order became final, however, Yong Hyun Kim d/b/a Minute Stop Market paid the assessed penalty and the Administrative Law Judge closed the case. Complaint ¶ 12.
- On June 6, 2012, FDA-commissioned inspectors observed another violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . at approximately 3:51 PM PT.” The inspectors also observed a violation of 21 C.F.R. § 1140.14(b)(1) when Respondent’s staff failed to verify, by means of photo identification containing the purchaser’s date of birth, that the purchaser of the Newport Box 100s cigarettes was 18 years of age or older. 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 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). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no purchasers of cigarettes or smokeless tobacco are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent violated regulations contained in 21 C.F.R. Part 1140 four times within a sixteen month period. Specifically, Respondent had a violation on February 17, 2011; a violation during a two-part inspection conducted on October 25, 2011, and November 7, 2011; and two violations on June 6, 2012. Respondent's actions violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions violated the law and merit a civil money penalty.

The regulations require me to impose 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 \$2,000 for a fourth violation within a sixteen month period and CTP has sought a penalty in that amount. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge