

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Highland Marina LLC,

Respondent.

Docket No. C-13-459
FDA Docket No. FDA-2013-H-0216

Decision No. CR2749

Date: April 8, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Highland Marina LLC, 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 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 and failed to verify the photo identification of a purchaser of cigarettes or smokeless tobacco, 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 February 26, 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 Highland Marina, an establishment that sells tobacco products and is located at 7878 Highway 34, Granby, CO 80446. Complaint ¶ 2.
- On August 22, 2011, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) at Respondent’s establishment when Respondent or staff sold cigarettes or smokeless tobacco to a person under 18 years of age. The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) at Respondent’s establishment when Respondent or staff failed to verify the photo identification of a purchaser of cigarettes or smokeless tobacco in order to ensure that no purchaser is less than 18 years of age. Complaint ¶ 9.
- On October 20, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from August 22, 2011. The letter explained that the observations constituted two violations of regulations found at 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1). The letter also stated that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment and that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by the FDA. *Id.*

- Laurie Hedgecock, owner of Highland Marina LLC, responded to the Warning Letter on Respondent's behalf via a telephone call on October 27, 2011. Ms. Hedgecock "stated that she trains employees to ask for ID from anyone purchasing tobacco products under 30 years of age and to refuse to sell to anyone under 18 years of age," and that she "would retrain the clerk who sold the cigarettes to the minor." Complaint ¶ 10.
- On July 12, 2012, FDA commissioned inspectors observed additional violations at Respondent's establishment. Inspectors observed a violation of 21 C.F.R. § 1140.14(a), when Respondent or staff sold a package of "Marlboro Gold Pack" cigarettes to a person younger than 18 years of age at approximately 11:20 AM MT. The inspectors also observed a violation of 21 C.F.R. § 1140.14(b)(1), when Respondent or staff failed to verify the photo identification of the purchaser during the 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 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 the photo identification, containing a date of birth, of purchasers of cigarettes or smokeless tobacco in order to ensure that no purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a twelve month period. Specifically, Respondent had two violations on August 22, 2011, and two violations on July 12, 2012. Respondent's actions violated regulations prohibiting the sale of cigarettes or smokeless tobacco to individuals younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions likewise violated regulations requiring retailers to verify the photo identification of purchasers of cigarettes or smokeless tobacco in order to ensure that no purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). 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 \$2,000 for four violations within a twelve month

period. 21 C.F.R. § 17.2. CTP, however, has requested a fine in the amount of \$500. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

_____/s/
Steven T. Kessel
Administrative Law Judge