

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Los Manueles Grocery Inc.,

Respondent.

Docket No. C-13-934
FDA Docket No. FDA-2013-H-0762

Decision No. CR2891

Date: August 19, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Los Manueles Grocery Inc., that alleges 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 that purchasers of cigarettes or smokeless tobacco were 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 \$500.

On June 28, 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 Los Manueles Grocery Inc., an establishment that sells tobacco products and is located at 1829 Wakeling Street, Philadelphia, Pennsylvania 19124. Complaint ¶ 3.
- On September 7, 2011, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a 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 . . . [.]” The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor's identification was not verified before the sale” Complaint ¶ 10.
- On December 8, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from September 7, 2011. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 1140.14(b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, a civil money penalty or other regulatory action by the FDA could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- FDA received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named

- “Abreu” received the Warning Letter on December 9, 2011. Complaint ¶ 11.
- FDA-commissioned inspectors documented two additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment on December 31, 2012, at approximately 12:13 PM ET. The inspectors documented a 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 . . . [.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor's identification was not verified before the sale” Complaint ¶ 1.
 - On January 8, 2013, CTP issued a Notice of Compliance Check Inspection to Respondent’s establishment due to a minor’s purchase of a regulated tobacco product on December 31, 2012, at approximately 12:13 PM ET. 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 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 the purchaser’s date of birth, that no purchasers of cigarettes are 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 sixteen-month period. Specifically, Respondent had two violations on September 7, 2011, and two violations on December 31, 2012. Respondent’s actions violated the prohibition against selling cigarettes 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 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 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. 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