

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

A.M.A. LLC d/b/a City Food Mart,

Respondent.

Docket No. C-13-492

FDA Docket No. FDA-2013-H-0246

Decision No. CR2758

Date: April 17, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, A.M.A. LLC d/b/a City Food Mart, 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 March 6, 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 City Food Mart, an establishment that sells tobacco products and is located at 442 Burnside Avenue, East Hartford, CT 06108. Complaint ¶ 3.
- On May 23, 2012, an FDA-commissioned inspector observed violations at Respondent’s establishment 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, and 21 C.F.R. § 1140.14(b)(1), a regulation requiring retailers to verify the age of a purchaser of cigarettes of smokeless tobacco by means of photo identification containing the purchaser’s date of birth. Complaint ¶ 10.
- On July 19, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from May 23, 2012. 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 failure to correct the violations 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.*

- FDA received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named “Scott” received the Warning Letter on July 20, 2012. Complaint ¶ 11.
- FDA commissioned inspectors observed two subsequent violations at Respondent’s establishment on November 2, 2012, at approximately 9:42 AM ET. Violations resulted from “a person younger than 18 years of age . . . purchas[ing] a package of Newport Box 100s cigarettes.” The purchase itself violated 21 C.F.R. § 1140.14(a), and an additional violation of 21 C.F.R. § 1140.14(b)(1) occurred when Respondent failed to verify the age of the purchaser by means of photographic identification containing the purchaser’s date of birth. Complaint ¶ 1.
- On November 12, 2012, CTP issued a Notice of Compliance Check Inspection to City Food Mart due to the violations on November 2, 2012, at approximately 9:42 AM ET. The Notice stated that the violations described were not necessarily the only violations 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). 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). Regulations also require retailers to verify, by means of photo identification containing the 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).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a six month period. Specifically, Respondent had two violations on May 23, 2012, and two violations on November 2, 2012. Respondent’s actions twice violated regulations prohibiting the sale of cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent’s actions also twice violated the requirement that retailers verify, by means of photo identification containing the 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 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 the fourth violation within a six 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