Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Mas Amigos, Inc.,

Respondent.

Docket No. C-13-686 FDA Docket No. FDA-2013-H-0489

Decision No. CR2818

Date: June 11, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Mas Amigos, Inc., 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 order that Respondent pay a civil money penalty in the amount 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's staff unlawfully sold regulated tobacco products to a minor or minors on two occasions and failed to verify the age of a tobacco purchaser prior to one of these transactions, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing

regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$500.

On May 1, 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 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 did not take any of the required actions within the time provided by regulation.

I am required to issue a default judgment if the Complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Mas Amigos, an establishment that sells tobacco products and is located at 607 North Cunningham Avenue, Urbana, Illinois, 61802.
- On May 15, 2012, an FDA-commissioned inspector observed a violation while inspecting Respondent's establishment. Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff sold tobacco products to a minor. Specifically, a person younger than 18 years of age was able to purchase a package of "Marlboro Gold Pack" cigarettes at 4:40 PM CT.
- On July 12, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from May 15, 2012. In addition to describing the violation, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violation. The letter also stated that it was Respondent's responsibility to comply with the law.
- On July 17, 2012, Juan Reyna, President, responded, in writing, to the Warning Letter on behalf of Respondent. Mr. Reyna stated that he had

spoken to his employees about the FDA's tobacco regulations and that his establishment would not sell tobacco products to minors in the future.

• On December 17, 2012, FDA-commissioned inspectors documented additional violations during another inspection of Respondent's establishment. At approximately 6:05 PM CT, the inspectors 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 "Marlboro Gold Pack" cigarettes. Additionally, the inspectors observed a violation of 21 C.F.R. § 1140.14(b)(1) when Respondent's staff failed to verify the minor's identification before this sale.

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 sold or distributed 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age.

Here, Respondent's staff sold cigarettes or smokeless tobacco to a minor or minors on two separate occasions; specifically, May 15, 2012, and December 17, 2012. In addition, Respondent's staff did not check the photographic identification of the tobacco purchasers prior to the December 17, 2012, transaction as required by the regulations. Respondent's actions and omissions on two occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$500 is permissible under 21 C.F.R. § 17.2 and order one imposed.

/s/

Steven T. Kessel Administrative Law Judge