

**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

