

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Cumberland Farms, Inc.
d/b/a Cumberland Farms #23,

Respondent.

Docket No. C-14-437
FDA Docket No. FDA-2013-H-1647

Decision No. CR3142

Date: March 5, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (“CTP”) filed an Administrative Complaint (“Complaint”) against Respondent, Cumberland Farms, Inc. d/b/a Cumberland Farms #23, alleging facts and legal authority sufficient to justify imposing 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 impermissibly sold cigarettes to minors and failed to verify that a cigarette purchaser was of sufficient age, 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 January 14, 2014, 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 by default 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 requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

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 Cumberland Farms #23, an establishment that sells tobacco products and is located at 76 City Hall Avenue, Gardner, Massachusetts 01440. Complaint ¶ 3.
- On May 22, 2013, during an inspection of Respondent's establishment, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Non-Menthol Box cigarettes . . . at approximately 4:22 PM." Complaint ¶ 10.
- On June 6, 2013, CTP issued a Warning Letter to Cumberland Farms #23 explaining that the inspector's May 22, 2013 observation constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a). 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 it failed to correct the violation. The letter also stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 10.
- On June 21, 2013, Michael Fleming, Respondent's Corporate Counsel, responded in writing to the Warning Letter on Respondent's behalf. "Mr. Fleming stated that the establishment trains all employees on its tobacco sales policy, and provides them with various training and reference

