

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Five Smooters, Inc.
d/b/a La Plata Short Stop,

Respondent.

Docket No. C-14-261
FDA Docket No. FDA-2013-H-1454

Decision No. CR3092

Date: January 28, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Five Smooters, Inc. d/b/a La Plata Short Stop (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and 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 person younger than 18 years of age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301 – 399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$500.

On December 3, 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 must take one of the following three actions: 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 issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act],” issue an initial decision and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns La Plata Short Stop, an establishment that sells tobacco products and is located at 12732 Old Highway 63, La Plata, Missouri 63549. Complaint ¶ 3.
- On February 4, 2013, CTP initiated a civil money penalty action against Respondent for two violations of 21 C.F.R. Part 1140 within a twelve-month period. *See* CRD Docket Number C-13-362, Complaint ¶ 13. Specifically, on March 2, 2012, an FDA-commissioned inspector observed that Respondent “[had] a basket containing packages of cigarettes located on the sales counter where the packages were directly accessible to consumers.” *Id.* at ¶ 10.
- During a subsequent “two-part inspection” conducted on November 5, 2012 and November 6, 2012, FDA-commissioned 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 Copenhagen Long Cut smokeless tobacco on November 5, 2012, at approximately 12:50 PM.” *Id.* at ¶ 1; Complaint ¶ 10.
- “Linda Smoot, [who] identified herself as being authorized to settle claims on behalf of Five Smooters, Inc. d/b/a La Plata Short Stop” settled CRD Docket Number C-13-362 and the case closed on March 11, 2013. Complaint ¶ 11.
- On May 20, 2013, FDA-commissioned inspectors documented a violation of 21 C.F.R. § 1140.14(a) at the establishment. Specifically, the inspectors observed that “a person younger than 18 years of age was able to purchase

