

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

S & D Petroleum, Inc.  
d/b/a Clark,

Respondent.

Docket No. C-13-1310  
FDA Docket No. FDA-2013-H-1113

Decision No. CR2994

Date: November 13, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, S & D Petroleum, Inc. d/b/a Clark, 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 cigarettes to minors and failed to verify that the cigarette purchasers were 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 September 17, 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 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 Clark, an establishment that sells tobacco products and is located at 3614 State Road 37, Mitchell, Indiana 47446. Complaint ¶ 3.
- On October 8, 2012, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Timber Wolf Long Cut Wintergreen smokeless tobacco . . . at approximately 6:29 PM . . . [.]” The inspector also noted that “the minor’s identification was not verified before the sale . . . on October 8, 2012 . . . .” Complaint ¶ 10.
- On November 29, 2012, CTP issued a Warning Letter to Respondent detailing the inspector’s observations from October 8, 2012. The letter explained that the inspector’s observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1). In addition to describing the violations, 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.
- United Parcel Service records show that “Haffner” received the Warning Letter on November 30, 2012, but the FDA did not receive a response to it. Complaint ¶ 11.

