

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

4000 Western Inc.  
d/b/a/ Western & Irving Mobil,

Respondent.

Docket No. C-13-395  
FDA Docket No. FDA-2013-H-0143

Decision No. CR2729

Date: March 22, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, 4000 Western Inc. d/b/a/ Western & Irving Mobil, 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 assess a civil money penalty of \$500.

CTP began this case by serving the 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 or smokeless tobacco to a minor or minors and impermissibly failed to verify the photo identification of a purchaser or purchasers of cigarettes or smokeless tobacco, thereby violating the Federal Food, Drug, and Cosmetic Act

(Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$500.

On February 11, 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 proposed 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 has not filed an answer within the time provided by regulation, nor has it timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Western & Irving Mobil, an establishment that sells tobacco products and is located at 4000 North Western Avenue, Chicago, IL 60618. Complaint ¶ 2.
- On September 6, 2011, an FDA-commissioned inspector observed two violations at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(a), a regulation prohibiting the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age. The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1), a regulation requiring retailers to verify the photo identification of a purchaser of cigarettes or smokeless tobacco in order to ensure that no person purchasing such products is under 18 years of age. Complaint ¶ 9.
- On December 8, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from September 6, 2011. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that failure to correct the violations could result in the imposition of a civil

money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. *Id.*

- FDA received a response to the Warning Letter from “Syed” on Respondent’s behalf. In a letter, he stated that he would ensure “that all employees are in compliance with city, state, and federal laws and regulations.” Complaint ¶ 10.
- On May 7, 2012, FDA commissioned inspectors documented further violations at Respondent’s establishment. A minor purchased a package of “Camel Blue” cigarettes at approximately 6:06 PM CT. Additionally, Respondent failed to verify the age of a purchaser of tobacco products by means of photographic identification containing the bearer's date of birth during the same transaction. Complaint ¶ 1.

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 distributed or offered for sale in any state 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). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations likewise require retailers to verify, by means of photographic identification containing the bearer’s date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent had four violations of regulations contained in 21 C.F.R. Part 1140 within a twelve month period. Specifically, Respondent had two violations on September 6, 2011, and two violations on May 7, 2012. Respondent’s actions on both dates violated regulations prohibiting the sale of cigarettes or smokeless tobacco to minors. 21 C.F.R. § 1140.14(a). Respondent’s actions on both dates also violated the requirement that retailers verify, by photo identification containing the bearer’s date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

The regulations require the imposition of a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$2,000 for four violations within a twelve month

period. 21 C.F.R. § 17.2. CTP, however, has requested a fine in the amount of \$500. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

\_\_\_\_\_/s/  
Steven T. Kessel  
Administrative Law Judge