

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Ghalayini LLC  
d/b/a George Street Deli,

Respondent.

Docket No. C-13-676  
FDA Docket No. FDA-2013-H-0467

Decision No. CR2822

Date: June 12, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Ghalayini LLC d/b/a George Street Deli, that alleges facts and legal authority sufficient to justify imposing a \$500 civil money penalty. 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 filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management and serving the Complaint on Respondent. The Complaint alleges that Respondent unlawfully sold tobacco products to minors and failed to verify that the purchasers of tobacco products were of sufficient 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 monetary penalty of \$500 for these violations.

On April 24, 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 issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. 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 a default judgment and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns George Street Deli, an establishment that sells tobacco products and is located at 802 George Street, New Haven, Connecticut 06511. Complaint ¶ 3.
- On June 26, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.14(a) for “[s]elling tobacco products to a minor” and a violation of 21 C.F.R. § 1140.14(b)(1) for “[f]ailing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer’s date of birth[.]” Complaint ¶ 10.
- “[O]n August 30, 2012, CTP issued a Warning Letter to George Street Deli.” Complaint ¶ 10. The letter noted the violations the FDA-commissioned inspector had observed on June 26, 2012, and explained that if Respondent failed to correct violations, it could face a civil money penalty or other regulatory action. Complaint ¶ 10. Moreover, CTP explained that the warning letter was not intended to provide an exhaustive list of violations and that George Street Deli was responsible for complying with the law. Complaint ¶ 10.
- Respondent’s owner responded to CTP by telephone on behalf of Respondent on September 5, 2012. Complaint ¶ 11. The owner informed

CTP that “the clerk who committed the violation had not been adequately trained and no longer worked at the establishment.” Complaint ¶ 11. The owner further explained that “he had discussed the violation with all staff so that future violations would not occur.” Complaint ¶ 11.

- On December 4, 2012, CTP acknowledged in writing that it had received Respondent’s response and reminded George Street Deli that it had a continuing duty to comply with the law. Complaint ¶ 11.
- During a subsequent inspection, FDA-commissioned inspectors documented two additional violations. Complaint ¶ 1. First, “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on December 19, 2012, at approximately 11:05 AM ET; and . . . the minor’s identification was not verified before the sale . . . .” Complaint ¶ 1.
- Thereafter, on December 26, 2012, CTP informed Respondent of the December 19, 2012, inspection and documented violations through a Notice of Compliance Check Inspection. The Notice warned “that other potential violations of federal tobacco law may have been observed,” and, if violations had occurred, FDA could notify Respondent further. Complaint ¶ 2.

Taking these facts as true, I must find, pursuant to 21 C.F.R. § 17.11(a), 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 sold or distributed in violation of regulations issued under section 906(d) of the Act, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those 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). Those regulations also require a retailer to “verify by means of photographic identification containing the bearer’s date of birth that no person purchasing the [tobacco] product is younger than 18 years of age[.]” 21 C.F.R. § 1140.14(b)(1).

Here, Respondent violated both 21 C.F.R. § 1140.14(a) and (b)(1) on two separate occasions. Most recently, on December 19, 2012, Respondent violated those regulations when it sold Newport Box 100s cigarettes to a minor without verifying that the purchaser was of sufficient age. Respondent had violated both 21 C.F.R. § 1140.14(a) and (b)(1) previously on June 26, 2012, when it sold tobacco products to a minor without verifying the purchaser’s age. Therefore, Respondent’s actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

