

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Chappys Drive Thru Convenience Store LLC,

Respondent.

Docket No. C-13-1252

FDA Docket No. FDA-2013-H-1053

Decision No. CR2986

Date: November 7, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Chappys Drive Thru Convenience Store LLC, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not 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 \$250.

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 tobacco products to minors and failed to verify that a purchaser of a tobacco product was of sufficient age, 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 \$250.

On September 4, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), 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 did not comply with one of the 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 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 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 Chappy’s Drive Thru Convenience Store, an establishment that sells tobacco products and is located at 157 West Main Street, Gas City, Indiana 46933. Complaint ¶ 3.
- On October 16, 2012, at approximately 2:35 PM, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase Grizzly Long Cut Wintergreen smokeless tobacco . . . [.]” The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor's identification was not verified before the sale” Complaint ¶ 10.
- On October 19, 2012, CTP issued a Notice of Compliance Check Inspection (Notice) to Chappy’s Drive Thru Convenience Store, due to the October 16, 2012 inspection. The Notice informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 2:35 PM” on October 16, 2012. Complaint ¶ 10.
- On November 29, 2012, CTP issued a Warning Letter to Respondent specifying the violations the inspector observed at the establishment on October 16, 2012. The letter warned Respondent that if it failed to correct

the violations, a civil money penalty could be imposed on it or other regulatory action by the FDA and that it was Respondent's responsibility to ensure compliance with the law. Initially, the CTP did not receive a response to the Warning Letter. "UPS records [reflect] that the letter was received on November 30, 2012, by 'Chapman.'" Complaint ¶ 11.

- On February 15, 2013, by letter, CTP notified Chappy's Drive Thru Convenience Store that it had not received a response to the Warning Letter and reaffirmed Respondent's "continuing obligation to be in compliance with Act and its implementing regulations." Subsequently, "[o]n February 19, 2013, by telephone message, an individual who identified himself as 'Bo' responded to the Warning Letter" on Respondent's behalf. In its Complaint, CTP summarized Bo's message as follows: "'Bo' stated that the establishment verifies the identification of all individuals who enter the store." Complaint ¶ 11.
- During a subsequent inspection, conducted on March 4, 2013, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent's establishment. Specifically, 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 Camel Crush cigarettes . . . at approximately 6:05 PM ET." Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection (Notice) to Chappy's Drive Thru Convenience Store on March 7, 2013, informing Respondent that an inspection had been conducted on March 4, 2013, and "that during this inspection a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 6:05 PM." Complaint ¶ 2.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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, codified at 21 U.S.C. § 387f(d). *See* 21 U.S.C. § 387(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 to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no person purchasing cigarettes is younger than 18 years of age. 21 C.F.R. 1140.14(b)(1).

