

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

B & H Food, Inc.
d/b/a A-1 Gulf,

Respondent.

Docket No. C-13-1175
FDA Docket No. FDA-2013-H-0963

Decision No. CR2962

Date: October 23, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, B & H Food, Inc. d/b/a A-1 Gulf, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$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 tobacco products to minors and failed to verify that cigarette purchasers were 18 years of age or older, 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 August 22, 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 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 A-1 Gulf, an establishment that sells tobacco products and is located at 483 Concord Street, Framingham, Massachusetts 01702. Complaint ¶ 3.
- On July 25, 2012, at approximately 11:16 AM ET, 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 a package of Marlboro cigarettes . . . [.]” 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.
- CTP issued a Warning Letter to Respondent on October 11, 2012, regarding the inspector’s observations from July 25, 2012. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 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 if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.

- FDA received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named “OBSN” received the Warning Letter on October 12, 2012. Neither did Respondent reply to a follow-up letter from FDA that United Parcel Service records indicate an individual named “HOBSON” received on December 12, 2012.¹ Complaint ¶ 11.
- On February 3, 2013, at approximately 1:33 PM ET, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The 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 Marlboro cigarettes . . . [.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to A-1 Gulf on February 6, 2013, due to the February 3, 2013 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 1:33 PM” on February 3, 2013. Complaint ¶ 2.

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 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 cigarettes purchasers are 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 six-month period. Specifically, Respondent had two violations on July 25, 2012, and two violations on February 3, 2013. Respondent’s actions on two occasions violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21

¹ In its Complaint, CTP alleges that “HOBSON” received the follow-up letter on December 12, 2013, a date that has not yet occurred. I infer that CTP attributed the follow-up letter to 2013 due to a typographical error, and that “HOBSON” received the letter on December 12, 2012.

