

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

FFJ Inc. d/b/a Dellwood Market,

and

Fuad Ali d/b/a Dellwood Market,

Respondents.

Docket No. C-14-656
FDA Docket No. FDA-2014-H-0185

Decision No. CR3191

Date: April 4, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated the above-captioned matter when it filed an Administrative Complaint for Civil Money Penalties (Complaint) dated February 7, 2014, with the Departmental Appeals Board, Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. CTP alleged that FFJ Inc. d/b/a Dellwood Market (FFJ Inc.) and Fuad Ali d/b/a Dellwood Market (Fuad Ali) violated the Federal Food, Drug, and Cosmetic Act (Act) and the Act's implementing regulations. CTP previously initiated a civil money penalty action against FFJ Inc. when it filed a Complaint on May 3, 2013 (CRD Docket Number C-13-719, FDA-2013-H-0517). That case ended when an administrative law judge issued an Initial Decision and Default Judgment imposing a civil money penalty in the amount of \$500

against FFJ Inc. Fuad Ali was not named as a respondent in the May 3, 2013 Complaint and was not personally subject to the \$500 civil money penalty. CTP now seeks to impose a \$5,000 civil money penalty against FFJ Inc. and Fuad Ali. For the reasons stated below, I impose a \$5,000 civil money penalty against Respondent FFJ Inc.; however, I dismiss, without prejudice, the February 7, 2014 Complaint against Fuad Ali.

I. Background and Factual Allegations set forth in the February 7, 2014 Complaint

On September 6, 2012, “CTP issued a Warning letter to Dellwood Market . . . citing a violation [of 21 C.F.R. pt. 1140] on June 28, 2012, and stating that failure to correct the violations may result in a civil money penalty action, or other regulatory action by FDA.” On May 3, 2013, CTP filed a Complaint alleging that FFJ Inc. committed two additional violations of 21 C.F.R. pt. 1140 on January 14, 2013. This cause of action concluded when an administrative law judge entered default judgment against FFJ Inc. and ordered it to pay a \$500 civil money penalty. February 7, 2014 Complaint ¶¶ 10-11; *FFJ Inc. d/b/a Dellwood Market*, DAB CR2832, at 2-3 (2013).¹

During a subsequent inspection, FDA-commissioned inspectors documented the following at Respondents’ establishment:

[A] person younger than 18 years of age was able to purchase a package of Decade Red Box cigarettes on August 28, 2013, at approximately 7:14 PM; and . . . the minor’s identification was not verified before the sale, as detailed above, on August 28, 2013, at approximately 7:14 PM.

February 7, 2014 Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served FFJ Inc. with the February 7, 2014 Complaint on February 12, 2014, via United Parcel Service. CTP alleged that both FFJ Inc. and Fuad Ali owned Dellwood Market and, based on the August 28, 2013 inspection, charged both Respondents with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor) and 21 C.F.R. § 1140.14(b)(1) (failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer’s date of birth). CTP asked the CRD to impose a \$5,000 civil money penalty based on a total of five alleged violations of the regulations in a 36-month period. February 7, 2014 Complaint ¶¶ 1, 3, 10, 13.

¹ Administrative decisions and rulings cited in this decision are accessible on the internet at: <http://www.hhs.gov/dab/decisions/index.html>.

The February 7, 2014 Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer, and stated that failure to file an answer could result in the imposition of a civil money penalty against Respondents. February 7, 2014 Complaint ¶¶ 14-22. Further, CRD sent FFJ Inc. an Initial Order informing FFJ Inc. of the requirement to file an answer to avoid a default judgment. CRD sent a form answer along with the Initial Order that FFJ Inc. could fill out and file with CRD. Neither Respondent filed an answer or requested an extension of time within the 30-day time period prescribed in 21 C.F.R. § 17.9.

II. Analysis

In order to initiate a civil money penalty action, CTP must “serv[e] on the respondent(s) a complaint. . . .” 21 C.F.R. § 17.5(a). If service of the complaint has been properly effected under the regulations and if a respondent does not file an answer within 30 days of service of the complaint, then:

[T]he presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

- (1) The maximum amount of penalties provided for by law for the violations alleged; or
- (2) The amount asked for in the complaint, whichever amount is smaller.

21 C.F.R. § 17.11(a). The regulations require that proof of service include “the name and address of the person on whom the complaint was served, and the manner and date of service” 21 C.F.R. § 17.7(b). A failure to file a timely answer means that “the respondent waives any right to a hearing and to contest the amount of the penalties and assessments” imposed in the initial decision. 21 C.F.R. § 17.11(b).

CTP submitted proof that it served the February 7, 2014 Complaint on FFJ Inc. via United Parcel Service on February 12, 2014. This method of service is permissible. *See* 21 C.F.R. § 17.7(b)(2). Therefore, it appropriate for me to adjudicate CTP’s charges against FFJ Inc.

Accepting the facts alleged in the February 7, 2014 Complaint as true, I conclude that those facts establish that FFJ Inc. is liable under the Act. *See* 21 U.S.C. §§ 333(f)(9), 387c(a)(7)(B), 387f(d); 21 C.F.R. §§ 1140.1(b), 1140.14. I further conclude that CTP’s request to impose a \$5,000 civil money penalty against FFJ Inc. is permissible based on the three previously adjudicated violations (*see FFJ, DAB CR2832 at 2-3*), and the two violations established in this case, which all occurred within 36 months. *See* 21 C.F.R. § 17.2.

In regard to Fuad Ali, CTP submitted no proof that it served the February 7, 2014 Complaint on him. CTP only submitted one receipt from the United Parcel Service, which indicated that CTP addressed the complaint to FFJ Inc. Similarly, CTP's cover letter to the February 7, 2014 Complaint was only addressed to FFJ Inc. and not Fuad Ali. Therefore, the receipt that CTP submitted from the United Parcel Service is insufficient to prove service on Fuad Ali. 21 C.F.R. § 17.7(b); *see also* 21 C.F.R. § 17.5(a) (indicating that CTP must "serv[e] on the respondent(s) a complaint . . ."). Because there is no proof that CTP served Fuad Ali with the February 7, 2014 Complaint, Fuad Ali has not failed to timely file an answer. *See* 21 C.F.R. § 17.9(a). Therefore, I cannot issue an initial decision and default judgment against Fuad Ali. *See* 21 C.F.R. § 17.11(a). Further, because CTP failed to effectuate service on Fuad Ali within a reasonable time, I will dismiss, without prejudice, the February 7, 2014 Complaint as it relates to Fuad Ali.

Even if service of the February 7, 2014 Complaint had been properly effectuated, I would have dismissed the Complaint against Fuad Ali because CTP failed to properly warn Fuad Ali before seeking to impose a civil money penalty against him.

There are two different civil money penalty structures applied to tobacco retailers who violate the Act. 21 C.F.R. § 17.2. The regulations separate tobacco retailers into two categories, retailers with approved training programs and retailers without approved training programs. *Id.* However, in the absence of regulations concerning approved training programs, CTP has adopted the practice of treating every tobacco retailer as if they have an approved training program. *Chambers Drive Inc., d/b/a Dynasty Deli Quick Stop*, ALJ Ruling 2012-3, at 2 n.3 (HHS CRD August 23, 2012); *see also* Complaint ¶ 12. When a tobacco retailer with an approved training program commits its initial violation of the regulations promulgated at 21 C.F.R. pt. 1140, CTP:

must give the retailer "timely and effective notice" of each alleged violation before it conducts a follow-up compliance check; it must also give notice of all previous violations before it can charge the retailer. TCA § 103(q)(1)(B), (D); 21 U.S.C. § 333 (Guidance); *see also* CTP Ex. 1 at 6 (Goldman Dec. ¶ 12). Consistent with these requirements, the FDA sends the retailer a warning letter the first time it finds a violation. That letter lists the alleged violations, warns of future inspections, and explains the consequences of future violations.

Chambers Drive, ALJ Ruling 2012-3, at 2. Therefore, a civil money penalty can only be imposed after issuance of the warning and an additional violation of the regulations by the retailer with an approved training program. *See* 21 C.F.R. § 17.2.

In the present matter, CTP did not allege that it provided Fuad Ali a warning prior to his alleged August 28, 2013 violation of 21 C.F.R. pt. 1140. *See* February 7, 2014 Complaint ¶¶ 1-10. Although in the February 7, 2014 Complaint CTP alleged that Fuad Ali owned Dellwood Market along with FFJ Inc., CTP made no such allegation in the May 3, 2013 Complaint. February 7, 2014 Complaint ¶¶ 10-11; *FFJ*, DAB CR2832, at 2-3. Therefore, I conclude that the record before me does not justify imposing a civil money penalty against Fuad Ali.

III. Conclusion

Based on the foregoing, I direct FFJ Inc. to pay a civil money penalty in the amount of \$5,000. Further, I dismiss, without prejudice, the February 7, 2014 Complaint as it relates to Fuad Ali. This initial decision becomes final and binding upon both parties 30 days after the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

/s/
Scott Anderson
Administrative Law Judge