**Department of Health and Human Services**
**DEPARTMENTAL APPEALS BOARD**
**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

E Market LLC

d/b/a EZ Market,

Respondent.

FDA Docket No. FDA-2019-H-0164

CRD Docket No. T-19-1130

Decision No. TB3994

Date: June 24, 2019

# INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i) as charged in the Complaint; and
2) Respondent committed three violations in a 24-month period as set forth hereinabove.
3) Respondent is hereby assessed a civil penalty in the amount of $559.

Glossary:

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|---|---|
| ALJ | administrative law judge[1] |
| CMP | civil money penalty |
| CTP/Complainant | Center for Tobacco Products |
| DJ | Default Judgment |
| FDCA | Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) |

[1] *See* 5 C.F.R. § 930.204.

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|---|---|
| DN | UPS Delivery Notification |
| FDA | Food and Drug Administration |
| HHS | Dept. of Health and Human Services |
| OSC | Order Granting Motion for Default and Order to Show Cause to Respondent |
| POS | UPS Proof of Service |
| SOP | Service of Process |
| Respondent | E Market LLC d/b/a EZ Market |
| TCA | The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)(TCA) |

## I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 *et seq.* and 21 C.F.R. Part 17.[2]

## II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on January 15, 2019 against E Market LLC d/b/a EZ Market (Respondent or EZ Market), at 35 East Main Street, Waterbury, Connecticut 06702 alleging that FDA documented three violations within a 24-month period.

Respondent did not file an answer to the Complaint by the regulatory deadline. On February 26, 2019, CTP filed a motion requesting a default judgment be entered against Respondent for failing to file an answer. Respondent was ordered to show cause,

[2] *See also Butz v. Economou*, 438 U.S. 478 at 513 (1978); *Marshall v. Jerrico, Inc*., 446 U.S. 238 (1980); *Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

no later than March 5, 2019, why a default judgment should not be entered in favor of CTP.

On March 4, 2019, Respondent filed a response which I accepted as its answer to CTP's Complaint. On March 7, 2019, I issued a pre-hearing order that set forth deadlines for parties' submissions, including an April 8, 2019 deadline to request documents from the opposing party. The order further set forth that, pursuant to 21 C.F.R. § 17.23(a), any documents requested must be provided to the opposing party within 30 days of the request.

On May 3, 2019, CTP filed a Motion to Compel Discovery. The motion stated that Respondent did not respond to CTP's Request for Production of Documents, and requested an order be entered against Respondent compelling Respondent to respond to CTP's request in its entirety. On May 30, 2019, I granted CTP's Motion to Compel Discovery and ordered Respondent to show cause, no later than June 10, 2019, why a default judgment should not be entered in favor of CTP. To date, Respondent has not filed a response to my May 30, 2019 order.

## III. SANCTIONS

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a party for:

(1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

Here, Respondent failed to comply with my March 7, 2019 pre-hearing order which ordered a party receiving a discovery request to provide the requested documents no later than 30 days after the request was made. Respondent also failed to respond to my May 30, 2019 Order to Show Cause. Respondent's failure to comply with my orders and procedures governing this proceeding constitutes misconduct that has interfered with the speedy, orderly, and fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). Accordingly, I find that sanctions are appropriate under 21 C.F.R. § 17.35.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's misconduct is sufficiently egregious to warrant striking its answer and issuing a default judgment without further proceeding. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

## IV. BURDEN OF PROOF

CTP as the petitioning party has the burden of proof. 21 C.F.R. § 17.33.

## V. LAW

21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i).

## VI. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i) as alleged in the Complaint?

## VII. DEFAULT

I find Respondent was served with the Complaint and is subject to the jurisdiction of this forum, as established by the Notice of Filing filed by CTP on January 16, 2019.

Striking Respondent's answer leaves the Complaint unanswered. 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, I must issue an initial decision and impose a civil money penalty.

## VIII. ALLEGATIONS

### A. Agency's recitation of facts

CTP alleged that Respondent owns an establishment, doing business under the name EZ Market, located at 35 East Main Street, Waterbury, Connecticut 06702. Respondent's establishment receives tobacco products in interstate commerce and holds them for sale after shipment in interstate commerce.

CTP's Complaint alleged that on May 24, 2018, CTP issued a Warning Letter to Respondent, alleging that Respondent committed the following violations:

a. Selling covered tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(b)(1). Specifically, a person younger than 18 years of age was able to purchase a package of two Garcia y Vega Game Mango cigars on March 27, 2018, at approximately 11:37 AM; and

b. Failing to verify the age of a person purchasing covered tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(2)(i). Specifically, the minor's

identification was not verified before the sale, as detailed above, on March 27, 2018, at approximately 11:37 AM.

Because no opportunity for a hearing was provided before the Warning Letter was issued, Respondent had a right to challenge the allegations in the Warning Letter in the instant case. *See Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

Further, during an inspection of EZ Market conducted on September 14, 2018, an FDA-commissioned inspector documented the following violations:

a. Selling covered tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(b)(1). Specifically, a person younger than 18 years of age was able to purchase a package of three Dutch Masters cigars on September 14, 2018, at approximately 9:20 AM; and

b. Failing to verify the age of a person purchasing covered tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on September 14, 2018, at approximately 9:20 AM.

B. Respondent's recitation of facts

I have struck Respondent's answer from the record, therefore, there are no responsive pleadings for me to consider and I assume those allegations set forth in the Complaint to be true. 21 C.F.R. § 17.11(a).

Therefore, under FDA's current policy, the violations described in the Complaint count as three violations for purposes of computing the civil money penalty in the instant case. I find and conclude Respondent committed three violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) and 21 C.F.R. § 1140.14(b)(2)(i), within a 24-month period as set forth in the Complaint.

## IX. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The "relevant statute" in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco sales. The Secretary's regulations on tobacco products appear in Part 1140 of Title 21, Code of Federal Regulations.

Under the FDCA, "[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d)." 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a) (2012). These regulations were

passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products; 75 Fed. Reg. 13,225 (Mar. 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that "failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act."

Under 21 U.S.C. § 331(k), "[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded" is a prohibited act under 21 U.S.C. § 331. Thus, when a retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from "any person who violates a requirement of this chapter which relates to tobacco products." 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2. Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin.*,

*Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2016), available at* *http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf*, at 13-14. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i), this will count as two separate violations for purposes of computing the civil money penalty, unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board to be consistent with the language of the FDCA and its implementing regulations, *see Orton Motor Co. d/b/a Orton's Bagley v. HHS*, 884 F.3d 1205 (D.C. Cir. 2018).

X. LIABILITY

When a retailer such as Respondent is found to have "misbranded" a tobacco product in interstate commerce, it can be liable to pay a CMP. 21 U.S.C. §§ 331, 333. A retailer facing such a penalty has the right, set out in statute, to a hearing under the Administrative Procedure Act. 21 U.S.C. § 333(f)(5)(A). A retailer can forfeit its rights under the statute and regulations by failing to participate in the process, a failure known as a "default." 21 C.F.R. § 17.11.

As set forth above, it is Respondent's right to decide whether to participate in the legal process. It is Respondent's right to decide to request a hearing and it is Respondent's right to waive a hearing.

I find Respondent, by failing to respond, waived its right to a hearing.

## XI. IMPACT OF RESPONDENT'S DEFAULT

When a Respondent defaults by failing to answer the complaint, or respond to a OSC, an ALJ must assume as true all factual allegations in the complaint and issue an initial decision within thirty (30) days of the answer's due date, imposing "the maximum amount of penalties provided for by law for the violations alleged" or "the amount asked for in the complaint, whichever is smaller" if "liability under the relevant statute" is established. 21 C.F.R. § 17.11(a)(1) and (2). *But see* 21 C.F.R. § 17.45 (initial decision must state the "appropriate penalty" and take into account aggravating and mitigating circumstances).

Two aspects of Rule 17.11 are important in default cases.

First, the Complainant benefits from a regulatory presumption (the ALJ shall assume that the facts alleged in the complaint are true) that relieves it from having to put on evidence.

The presumption affords a party, for whose benefit the presumption runs, the luxury of not having to produce specific evidence to establish the point at issue. When the predicate evidence is established that triggers the presumption, the further evidentiary gap is filled by the presumption. *See* 1 *Weinstein's Federal Evidence* § 301.02[1], at 301-7 (2d ed.1997); 2 *McCormick on Evidence* § 342, at 450 (John W. Strong ed., 4th ed. 1992); *Routen v. West*, 142 F.3d 1434, 1440 (Fed. Cir. 1998).[3]

[3] However, when the opposing party puts in proof to the contrary of that provided by the presumption, and that proof meets the requisite level, the presumption disappears. *See*

Second, as far as the penalty is concerned, my discretion is limited by the language of the regulation. I may not tailor the penalty to address any extenuation or mitigation, for example, nor, because of notice concerns, may I increase the penalty beyond the smaller of (a) the Complainant's request or (b) the maximum penalty authorized by law.

## XII. LIABILITY UNDER THE RELEVANT STATUTE

Taking the CTP's allegations as set forth in the Complaint as true, the next step is whether the allegations make out "liability under the relevant statute." 21 C.F.R. § 17.11(a).

Based on Respondent's failure to answer I assume all the allegations in the Complaint to be true.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) in that a person younger than 18 years of age was able to purchase covered tobacco products on March 27, 2018 and September 14, 2018.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R.

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*Texas Dept. of Community Affairs v. Burdine*, 450 U.S. 248, 254–55, 101 S.Ct. 1089, 1094–95, 67 L.Ed.2d 207 (1981); *A.C. Aukerman*, 960 F.2d at 1037 ("[A] presumption ... completely vanishes upon the introduction of evidence sufficient to support a finding of the nonexistence of the presumed fact."); *see also Weinstein's Federal Evidence* § 301App.100, at 301App.–13 (explaining that in the "bursting bubble" theory once the presumption is overcome, then it disappears from the case); 9 *Wigmore on Evidence* § 2487, at 295–96 (Chadbourn rev.1981). *See generally* Charles V. Laughlin, *In Support of the Thayer Theory of Presumptions*, 52 Mich. L.Rev. 195 (1953); *Routen v. West*, 142 F.3d 1434, 1440 (Fed. Cir. 1998).

§ 1140.14(b)(2)(i) on those same dates in that Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no covered tobacco product purchasers are younger than 18 years of age.

The conduct set forth above on March 27, 2018 and September 14, 2018 counts as three violations for purposes of computing the civil money penalty.

## XIII. PENALTY

There being liability under the relevant statute, I must now determine the amount of penalty to impose. My discretion regarding a penalty is constrained by regulation. I must impose either the maximum amount permitted by law or the amount requested by the Center, whichever is lower. 21 C.F.R. § 17.11(a)(1), (a)(2).

In terms of specific punishments available, the legislation that provides the basis for assessing civil monetary penalties divides retailers into two categories: those that have "an approved training program" and those that do not. Retailers with an approved program face no more than a warning letter for their first violation; retailers without such a program begin paying monetary penalties with their first. TCA § 103(q)(2), 123 Stat. 1839, *codified at* 21 U.S.C. § 333 note. *See* 21 C.F.R. § 17.2. The FDA has informed the regulated public that "at this time, and until FDA issues regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule." FDA Regulatory Enforcement Manual, Aug. 2015, ¶ 5-8-1. Because of this reasonable exercise of discretion, the starting point for punishments and the rate at which they mount are clear – the lower and slower schedules.

## XIV. MITIGATION

It is incumbent upon Respondent to present any factors that could result in mitigation of CTP's proposed penalty. Specifically, it is Respondent's burden to provide mitigating evidence. In a default, Respondent has failed to participate and has failed to present any evidence regarding potential mitigation. Accordingly, I have no reason to mitigate the penalty.

## XV. CONCLUSION

Respondent committed three violations in a 24-month period and so, Respondent is liable for a civil money penalty of $559. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby ORDERED as follows:

a. I find Respondent has been served with process herein and is subject to this forum.
b. I find Respondent failed to comply with my March 7, 2019 Pre-hearing Order and failed to respond to my May 30, 2019 Order to Show Cause.
c. I find Respondent is in default.
d. I assume the facts alleged in the Complaint to be true.
e. I find the facts set forth in the Complaint establish liability under the relevant statute.
f. I assess a monetary penalty in the amount of $559.

_____/s/_____
Richard C. Goodwin
U.S. Administrative Law Judge