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

Center for Tobacco Products,
Complainant

v.

JCG, Inc.
d/b/a Fresh Mart and Deli,
Respondent

FDA Docket No. FDA-2015-H-4689
CRD Docket No. T-17-412

Decision No. TB1349

Date: May 25, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1)[1] and 21 C.F.R. § 1140.14 (a)(2)(i) as charged in the complaint; and
2) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. 1140.14(a)(1), 21 C.F.R. § 1140.14(a)(2)(i), and 21 C.F.R. § 1140.16(c) as charged in the prior complaint; and
3) Respondent committed six (6) violations in a 48-month period as set forth hereinabove.
4) Respondent is hereby assessed a civil penalty in the amount of $11,000.

[1] On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.

Glossary:

ALJ	administrative law judge[2]
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)
DN	UPS Delivery Notification
FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
POS	UPS Proof of Service
SOP	Service of Process
Respondent	JCG, Inc. d/b/a Fresh Mart and Deli
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.[3]

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed an amended Complaint on December 7, 2016 alleging that FDA documented six (6) violations within a 48-month period.

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[2] *See* 5 C.F.R. § 930.204.

[3] *See also Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (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).

JCG, Inc. d/b/a Fresh Mart and Deli (Respondent or Fresh Mart and Deli) was served with process on November 17, 2016 by United Parcel Service. Respondent answered the Complaint on December 9, 2016. I issued a Procedural Order on February 15, 2017 that set deadlines for parties' submissions, including the March 17, 2017 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the Procedural Order stated that a party receiving such a request must provide the requested documents no later than 30 days after the request.

On April 25, 2017, CTP filed a Motion to Compel Discovery. CTP indicated that Respondent had not responded to a Request for Production of Documents that CTP sent to Respondent on March 17, 2017. On April 28, 2017, I issued an Order to Show Cause, instructing Respondent to show cause for its failure to respond to CTP's Request for Production of Documents by May 3, 2017. In the Order to Show Cause, I warned Respondent that failure to respond may result in sanctions. Respondent did not respond to my April 28, 2017 Order to Show Cause.

III. BURDEN OF PROOF

The Center for Tobacco Products (CTP/Complainant) as the petitioning party has the burden of proof (21 C.F.R. § 17.33).

IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a), 1140.14 (b)(1), and 1140.16(c).

V. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a), 1140.14 (b)(1), and 1140.16(c) as alleged in the complaint?

VI. DEFAULT

I find Respondent was served and is subject to the jurisdiction of this forum, as established by the UPS Delivery Notification filed by CTP and Respondent's answer to CTP's complaint. My Order instructed Respondent to Show Cause on or before close of business on May 3, 2017, why Judgment of Default (DJ) for its failure to respond to CTP's Request for Production of documents.

Respondent failed to comply with my Procedural Order and my April 28, 2017 Order to Show Cause.

It is Respondent's right to participate in the legal process.

It is Respondent's right to request a hearing or to waive a hearing.

I find Respondent, by failing to comply with my Orders, waived its right to a hearing.

VII. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Fresh Mart and Deli, located at 2418 North Central Street, Knoxville, Tennessee 37917. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Fresh Mart and Deli conducted on September 5, 2015, an FDA-commissioned inspector documented the following violations:

a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than l8 years of age was able to purchase a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco on September 5, 2015, at approximately 10:42 AM; and

b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale.

B. Prior Violations

On March 23, 2017, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2015-H-0891, against Respondent for four (4) violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent's business establishment, 2418 North Central Street, Knoxville, Tennessee 37917.

The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions"

I find and conclude Respondent committed six (6) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), 21 C.F.R. § 1140.14(a)(2)(i), and 21 C.F.R. § 1140.16(c) within a 48-month period as set forth in the complaint.

C. Striking Respondent's Answer

Due to noncompliance with my Procedural Order, and my April 28, 2017 Order to Show Cause, I am striking Respondent's answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. § 17.35(a)(1), 17.35(c) (3), 17.11(a). The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

Striking Respondent's answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my orders. 21 C.F.R. § 17.11.

Therefore, under FDA's current policy, the violations described in the Complaint counts as six (6) violation(s) for purposes of computing the civil money penalty in the instant case. *See Guidance for Industry*, at 13-15.

I find and conclude Respondent committed six (6) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1), 21 C.F.R. § 1140.14(a)(2)(i), and 21 C.F.R. § 1140.16(c) within a 48-month period as set forth in the Complaint.

VIII. 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 387 a-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 (March 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) (2015), available at *http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf* [hereinafter *Guidance for Industry*], at 13-15. 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) and (b)(1), 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 CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016.

IX. 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 comply with my Procedural Order and April 28, 2017 Order to Show Cause, waived its right to a hearing.

X. IMPACT OF RESPONDENT'S DEFAULT

Because striking a Respondent's answer leaves the Complaint unanswered, an ALJ must assume as true all factual allegations in the complaint and issue an initial decision, 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).[4]

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.

XI. 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 comply with my Orders 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 that Respondent violated 21 U.S.C. § 331, specifically 21

[4] 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 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 (1998) at 1440.

C.F.R. § 1140.14(a) in that a person younger than 18 years of age was able to purchase tobacco products on July 12, 2014, October 8, 2014, and September 5, 2015.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) on October 8, 2014 in that Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding that Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.16(c) on October 20, 2014 in that Respondent used a self-service display in a non-exempt facility to sell a tobacco product.

The conduct set forth above on July 12, 2014, October 8, 2014, October 20, 2014 and September 5, 2015 counts as six (6) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15.

XII. 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.

XIII. MITIGATION

Because Respondent is found to be in default I am required to impose the maximum amount of penalties provided for by law for the violations alleged. Therefore, no mitigation is considered.

XIV. CONCLUSION

Respondent committed six (6) violations in a 48-month period and so, Respondent is liable for a civil money penalty of $11,000. *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 Procedural Order, and my April 28, 2017 Order to respond to CTP's Motion to Compel.
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 $11,000.

/s/
Richard C. Goodwin
Administrative Law Judge