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

Center for Tobacco Products,
Complainant

v.

Jay Swaminarayn Corp.
d/b/a Hyanni's Food Mart,
Respondent

FDA Docket No. FDA-2017-H-5758
CRD Docket No. T-17-6602

Decision No. TB2693

Date: May 2, 2018

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) and 21 C.F.R. § 1140.14(a)(2)(i) as charged in the prior complaint; and
3) Respondent committed five (5) violations in a 36-month period as set forth hereinabove.
4) Respondent is hereby assessed a civil penalty in the amount of $5,591.

[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	Jay Swaminarayn Corp. d/b/a Hyanni's Food Mart
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)

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]

[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).

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on September 26, 2017 alleging that FDA documented five (5) violations within a 36-month period.

Jay Swaminarayn Corp. d/b/a Hyanni's Food Mart (Respondent or Hyanni's Food Mart) was served with process on September 20, 2017 by United Parcel Service. On October 17, 2017, Respondent filed a timely request for an extension to file an answer, and on October 19, 2017, I granted that request, providing Respondent an additional 30 days to respond. On November 20, 2017, Respondent answered the Complaint. I issued an Acknowledgment and Pre-Hearing Order (APHO) on November 24, 2017 that set deadlines for parties' submissions, including a December 27, 2017 deadline to request documents from the opposing party.[4] The APHO 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 February 9, 2018, CTP served Respondent with a Request for Production of Documents (RFP). On March 19, 2018, CTP filed a Motion to Compel Discovery, indicating that Respondent had not responded to its RFP. On that same day, I issued an Order granting CTP's Motion to Compel Discovery and ordering Respondent, by March 26, 2018, to: 1) show cause for its failure to respond to CTP's RFP; and 2) to produce

[4] The December 27, 2017 document request deadline was extended to February 12, 2018, after I granted CTP's "Unopposed Motion to Extend Deadlines and Notice of Pending Settlement" on November 30, 2017.

the documents requested by CTP. The Order warned Respondent that failure to comply with my order may result in the imposition of sanctions.

On April 11, 2018, CTP filed a Motion to Impose Sanctions. The Motion asserted that Respondent failed to comply with my March 19, 2018 Order. Because of Respondent's non-compliance, CTP argued that I should strike Respondent's November 20, 2017 Answer and issue a Default Judgment in the amount of $5,591.

To date, Respondent has not provided any response to my March 19, 2018 Order as to why it failed to provide CTP with timely discovery nor has it responded to CTP's Motion to Impose Sanctions.

III. SANCTIONS (STRIKING RESPONDENT'S ANSWER)

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 did not provide any response to CTP's February 9, 2018 Request for Production of Documents. Respondent also failed to comply with my Acknowledgment and Pre-Hearing Order and my March 19, 2018 Order. Respondent has failed to comply with my orders and procedures governing this proceeding which 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 the November 20, 2017 answer and issuing a decision without further proceeding. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

IV. 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).

V. LAW

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

VI. ISSUE

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

VII. DEFAULT

I find Respondent was served and is subject to the jurisdiction of this forum, as established by the UPS Delivery Notification and Notice of Filing filed by CTP and Respondent's answer to CTP's complaint. My Order Granting Motion to Compel, dated March 19, 2018, instructed Respondent to show cause on or before March 26, 2018 why it failed to respond to CTP's Request for Production of Documents.

Respondent failed to comply with my Acknowledgment and Pre-Hearing Order

and my March 19, 2018 Order. Thus, I strike Respondent's Answer as a sanction pursuant to 21 C.F.R. § 17.35(c)(3). Striking Respondent's Answer leaves the Complaint unanswered.

VIII. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Hyanni's Food Mart, located at 18 Center Street, Barnstable, Massachusetts 02601. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

During an inspection of Hyanni's Food Mart conducted on August 1, 2017, 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 18 years of age was able to purchase a package of Marlboro Gold Pack 100's cigarettes on August 1, 2017, at approximately 1:04 p.m.; 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, as detailed above, on August 1, 2017, at approximately 1:04 p.m.

B. Respondent's recitation of facts

I struck Respondent's Answer dated November 20, 2017. Accordingly, there are no responsive pleadings that I may consider.

IX. PRIOR VIOLATIONS

On May 3, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-2949, FDA Docket Number FDA-2017-H-1651, against Respondent for three[5] 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, 18 Center Street, Barnstable, Massachusetts 02601, on January 15, 2016, and December 8, 2016.

The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon 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 five (5) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i) within a 36-month period as set forth in the Complaint.

[5] An FDA-commissioned inspector documented two violations on January 15, 2016, (sale of tobacco products to a minor (21 C.F.R. § 1140.14(a)(1)) and failure to verify the age of the person purchasing tobacco products (21 C.F.R. § 1140.14(a)(2)(i))), and two violations on December 8, 2016, (sale of tobacco products to a minor (21 C.F.R. § 1140.14(a)(1)) and failure to verify the age of the person purchasing tobacco products (21 C.F.R. § 1140.14(a)(2)(i))). In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

X. 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) (2016), available at* *http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf* [hereinafter Guidance for Industry], 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.*, DAB No. 2717 (2016); *pet. for rev. denied*, 2018 WL 1386141 (D.C. Cir., Mar. 20, 2018).

XI. 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)).

As Respondent failed to respond to my orders, I strike Respondent's answer and find Respondent waived its right to a hearing.

XII. 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).[6]

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.

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[6] 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, 1440 (Fed. Cir. 1998).

XIII. 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)).

As striking Respondent's Answer has left the Complaint unanswered, 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 C.F.R. § 1140.14(a)(1) in that a person younger than 18 years of age was able to purchase cigarettes and/or smokeless tobacco on January 15, 2016, December 8, 2016, and August 1, 2017.

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(a)(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 cigarette and/or smokeless tobacco purchasers are younger than 18 years of age.

The conduct set forth above on January 15, 2016, December 8, 2016, and August 1, 2017 counts as five (5) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14.

XIV. 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.

XV. 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.

XVI. CONCLUSION

Respondent committed five (5) violations in a 36-month period and so, Respondent is liable for a civil money penalty of $5,591. *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 Acknowledgment and Pre-Hearing Order and my March 19, 2018 Order and, due to Respondent's failure to comply with my orders, I have stricken its November 20, 2017 Answer.
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 $5,591.

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