

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

Center for Tobacco Products,
Complainant

v.

Amir, Inc.
d/b/a Wild Bill's Tobacco / Smokers Outlet of New Hudson,
Respondent

FDA Docket No. FDA-2017-H-6024
CRD Docket No. T-18-28

Decision No. TB2588

Date: April 4, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1); 21 C.F.R. § 1140.14(b)(2)(i); and 21 C.F.R. § 1140.16(c) as charged in the complaint; and
- 2) Respondent committed four (4) violations in a 24-month period as set forth hereinabove.
- 3) Respondent is hereby assessed a civil penalty in the amount of \$2,236.

Glossary:

ALJ	administrative law judge ¹
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment

¹ See 5 C.F.R. § 930.204.

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	Amir, Inc. d/b/a Wild Bill's Tobacco / Smokers Outlet of New Hudson
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 17.²

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) filed a Complaint on October 10, 2017 alleging that FDA documented four (4) violations within a 24-month period.

² 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).

Amir, Inc. d/b/a Wild Bill's Tobacco / Smokers Outlet of New Hudson (Respondent or Wild Bill's Tobacco / Smokers Outlet of New Hudson) was served with process on October 6, 2017 by United Parcel Service. On November 1, 2017, Respondent answered the Complaint. I issued an Acknowledgment and Pre-Hearing Order (APHO) on November 2, 2017 that set deadlines for parties' submissions, including a December 4, 2017 deadline to request that the opposing party provide copies of documents relevant to this case. 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 December 1, 2017, CTP served Respondent with a Request for Production of Documents (RFP). On January 3, 2018, Respondent filed a Request to Extend Discovery, requesting that its deadline to respond to CTP's RFP be extended to January 31, 2018. Respondent's request for an extension noted that CTP did not oppose such an extension. On January 3, 2018, I issued an order granting Respondent's request.

On February 2, 2018, Respondent filed a Second Request to Extend Discovery, requesting that its deadline to respond to CTP's December 1, 2017 RFP be extended further to February 13, 2018. Respondent's request noted that CTP did not oppose such an extension. On February 5, 2018, I issued an order granting Respondent's request.

On February 20, 2018, CTP filed a Motion to Compel Discovery. CTP indicated that, despite being provided with two extensions of time to respond, Respondent had not responded to CTP's December 1, 2017 RFP. Also, on February 20, 2018, CTP filed a

separate Motion to Stay Deadlines pending the resolution of the discovery dispute.³ On February 21, 2018, I issued an Order granting CTP's Motion to Compel Discovery and ordering Respondent, by February 27, 2018, to: 1) show cause for its failure to respond to CTP's RFP; and 2) to produce the documents requested by CTP. The Order warned Respondent that failure to comply with my order may result in the imposition of sanctions.

On March 14, 2018, CTP filed a Motion to Impose Sanctions. The Motion asserted that Respondent failed to defend the action and did not comply with my Order. In its motion, CTP asked that I strike Respondent's November 1, 2017 Answer and issue a Default Judgment in the amount of \$2,236.

On March 16, 2018, Respondent submitted a response to CTP's December 1, 2017 Request for Production of Documents, 17 days after the deadline established in my Order. To date, Respondent has not provided any response to CTP's Motion to Impose Sanctions, nor has it provided any response my Order as to why it failed to provide CTP with timely discovery.

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 Pursuant to the February 5, 2018 Order granting Respondent's second extension request, that deadline had been extended to March 19, 2018.

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

Here, Respondent did not provide a timely response to CTP's December 1, 2017 Request for Production of Documents, even though it was granted two extensions in order to do so. Respondent also failed to comply with my Acknowledgment and Pre-Hearing Order and my February 21, 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 1, 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(b)(1); 21 C.F.R. § 1140.14(b)(2)(i); and 21 C.F.R. § 1140.16(c).

VI. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1); 21 C.F.R. § 1140.14(b)(2)(i); and 21 C.F.R. § 1140.16(c) 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 February 21, 2018, instructed Respondent to show cause on or before February 27, 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 February 21, 2018 Order. Thus, I struck 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 Wild Bill's Tobacco / Smokers Outlet of New Hudson, located at 30436 Milford Road, New Hudson, Michigan 48165. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's complaint alleged that, on December 8, 2016, 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 Swisher Sweets Tropical Fusion cigars on November 30, 2016, at approximately 6:32 p.m.; 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 November 30, 2016, at approximately 6:32 p.m.

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.*, Departmental Appeals Board (DAB) No. 2717, at 25 (2016), *pet. for rev. denied*, 2018 WL 1386141 (D.C. Cir., Mar. 20, 2018).

Further, during a two-part inspection of Wild Bill's Tobacco / Smokers Outlet of New Hudson conducted on September 13 and 20, 2017, 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 five Swisher Sweets Grape cigars on September 13, 2017, at approximately 4:50 p.m.;
- 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 13, 2017, at approximately 4:50 p.m.; and

c. Using a self-service display in a non-exempt facility, in violation of 21 C.F.R. § 1140.16(c). Specifically, on September 20, 2017, the inspector observed Starr smokeless tobacco, Red Man smokeless tobacco, Bowies smokeless tobacco, Bugler cigarette tobacco, Tube Cut Gambler cigarette tobacco, Rave cigarette tobacco, and Natural American Spirit cigarette tobacco, for sale from customer-accessible displays on the main sales floor. Additionally, on September 13, 2017, a person younger than 18 years of age was able to enter the establishment and purchase a regulated covered tobacco product.

Therefore, this facility does not qualify as one where minors are not permitted to enter at any time.

B. Respondent's recitation of facts

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, 17.35(a)(1).

Therefore, under FDA’s current policy, the violations described in the Complaint counts as four (4) violations for purposes of computing the civil money penalty in the instant case. *See 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.

I find and conclude Respondent committed four (4) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1); 21 C.F.R. § 1140.14(b)(2)(i); and 21 C.F.R. § 1140.16(c) 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 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 *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).

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)).

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

XI. 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 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).⁴

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

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 November 30, 2016 and September 13, 2017.

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)(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.

§ 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).

Finally, I also 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), in that, on September 20, 2017, Respondent was documented using a self-service display in a non-exempt facility.

The conduct set forth above on November 30, 2016, September 13, 2017 and, September 20, 2017 counts as four (4) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-14.

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

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.

XV. CONCLUSION

Respondent committed four (4) violations in a 24-month period and so, Respondent is liable for a civil money penalty of \$2,236. *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 February 21, 2018 Order.
- 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 \$2,236.

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