

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

Center for Tobacco Products,
Complainant

v.

Jian Kang Jiang
d/b/a China House Jiang's Restaurant,
Respondent

FDA Docket No. FDA-2017-R-5844
CRD Docket No. T-17-6677

Decision No. TB2419

Date: February 5, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

Found:

- 1) Respondent violated 21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i) as charged in the complaint; and
- 2) Respondent committed six repeated violations in a 36-month period as set forth hereinabove.
- 3) Respondent is hereby assessed No-Tobacco-Sale-Order for a period of 30 consecutive days.

Glossary:

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.

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	Jian Kang Jiang d/b/a China House Jiang's Restaurant
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 September 28, 2017 alleging that FDA documented six repeated violations within a 36-month period.

Jian Kang Jiang d/b/a China House Jiang's Restaurant (Respondent or China House Jiang's Restaurant) was served with process on September 25, 2017 by United Parcel Service. Respondent answered the Complaint on October 6, 2017. I issued an Acknowledgment and Pre-Hearing Order on October 16, 2017 that set deadlines for parties' submissions, including the November 13, 2017 deadline to request that the opposing party provide copies of documents relevant to this case.

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).

On December 15, 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 November 9, 2017. On that same date, CTP also filed a Motion to Extend Deadlines. On December 18, 2017, I issued an Order instructing Respondent to show cause for its failure to respond to CTP's Request for Production of Documents by December 22, 2017. In that Order, I warned Respondent that failure to respond may result in sanctions. Respondent did not respond to my December 18, 2017 Order.

On January 10, 2017, CTP filed Complainant's Motion to Impose Sanctions. The Motion asserted that Respondent failed to defend the action and did not comply with my December 18, 2017 Order. In its motion, CTP asked that I strike Respondent's October 6, 2017 Answer and issue a Default Judgment in the form of a No-Tobacco-Sale-Order for a period of 30 consecutive days. On January 12, 2018, I issued an Order instructing Respondent to show cause on or before January 20, 2018 why I should not strike Respondent's Answer and "issue an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a No-Tobacco-Sale-Order for 30 days." To date, Respondent has not shown cause.

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 respond to CTP's November 9, 2017 Request for Production of Documents. Respondent also failed to comply with my Acknowledgment and Pre-Hearing Order, my December 18, 2017 Order, and my January 12, 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, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). 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 October 6, 2017 Answer and issuing a decision without further proceeding. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

IV. LAW

21 C.F.R. §§ 1140.14(a)(1) and 1140.14(a)(2)(i).³

V. ISSUE

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

VI. DEFAULT

³ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

Section 17.7(a) provides that service of a complaint may be made in one of two ways: either by certified or registered mail or similar mail delivery service (i.e., one which provides a return receipt record reflecting receipt), or by delivery in person. 21 C.F.R. §§ 17.1(a)(1) and (a)(2). Delivery in person must be to either an individual respondent or to an “officer or managing or general agent in the case of a corporation or unincorporated business.” 21 C.F.R. §§ 17.7(a)(2)(i) and (a)(2)(ii). If the complaint is served by certified or registered mail or similar mail delivery service, proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service must be provided. 21 C.F.R. § 17.7(b). Nothing in the regulations require me to assume that a UPS Delivery Notification proves that the parcel delivered to Respondent contained the complaint and not any other printed or non-printed matter handled by the carrier or nothing at all. *See T and M United Corporation d/b/a BP Shop*, DAB No. 2705 (2016). Respondent may, in its response or answer to the complaint, raise a challenge to jurisdiction or defective service. However, if Respondent files a response or answer that does not specifically challenge jurisdiction, then Respondent is considered served and subject to the jurisdiction of this Court.

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 January 12, 2018 Order instructed Respondent to show cause on or before January 20, 2018, why Default Judgment should not be entered for failure to comply with the applicable rules.

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

my December 18, 2017 Order, and my January 12, 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.

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 file a responsive pleading, 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 China House Jiang's Restaurant, located at 1441 Snyder Avenue, Philadelphia, Pennsylvania 19145. CTP further alleged that during an inspection of China House Jiang's Restaurant conducted on May 3, 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 Newport Box 100s cigarettes on May 3, 2017, at approximately 12:30 PM; 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 May 3, 2017, at approximately 12:30 PM.

B. Respondent's recitation of facts

I struck Respondent's October 6, 2017 Answer.

Accordingly, Respondent has filed no responsive pleadings that I may consider.

VIII. PRIOR VIOLATIONS

On May 19, 2016, CTP initiated its first CMP action against Respondent,⁴ CRD Docket Number T-16-459, FDA Docket Number FDA-2016-H-0858, for three violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 1441 Snyder Avenue, Philadelphia, Pennsylvania 19145, on March 30, 2015 and November 13, 2015.⁵

The first CMP action concluded in settlement where Respondent "admitted all of the allegations in the Complaint and paid the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

On March 1, 2017, CTP initiated its second CMP, CRD Docket Number T-17-2396, FDA Docket Number FDA-2017-H-1030, for five violations of 21 C.F.R. pt. 1140

⁴ The first CMP and second CMP actions captioned the Respondent as Jian Kang Kiang, d/b/a China House.

⁵ An FDA-commissioned inspector documented two original violations on March 30, 2015 for the 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 repeated violations on November 13, 2015, for the 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)). The original violations are not included in this action.

within a 36-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 1441 Snyder Avenue, Philadelphia, Pennsylvania 19145, on September 7, 2016.⁶

The second CMP action concluded in settlement where Respondent "admitted all of the allegations in the Complaint and paid the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions."

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, I find and conclude Respondent committed six repeated violations of 21 C.F.R. pt 1140, specifically three repeated violations of 21 C.F.R. § 1140.14(a)(1) and three repeated violations of 21 C.F.R. § 1140.14(a)(2)(i) based on the conduct 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

⁶ An FDA-commissioned inspector documented two repeated violations on September 7, 2016 for the 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)).

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 CTP v. Orton Motor Company, DAB No. 2717 (2016).

X. LIABILITY

When a retailer such as Respondent is found to have committed six or more repeated violations of regulations within a 36-month period, a No-Tobacco-Sale-Order may be imposed. 21 U.S.C. § 333(f)(8); *See also* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3,5-6, *available at*

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>.

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

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).⁷

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

⁷ 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 at 1440 (1998).

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 committed three repeated violations of 21 C.F.R. § 1140.14(a)(1) in that a person younger than 18 years of age was able to purchase tobacco products on November 13, 2015, September 7, 2016, and May 3, 2017.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent committed three repeated violations of 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 tobacco product purchasers are younger than 18 years of age.

The conduct set forth above on November 13, 2015, September 7, 2016, and March 3, 2017 counts as six repeated violations.

XIII. PENALTY

There being liability under the relevant statute, I must now determine the appropriate penalty to impose. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed

“repeated violations” of restrictions on the sale of tobacco products, promulgated under section 387f(d). 21 U.S.C. § 333(f)(8). The term “repeated violations” is defined to mean “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet” *See* FDA Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers: Guidance for Industry (December 2016) at 3,5-6, *available at* <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm>.

In its Complaint, CTP sought a thirty day NTSO against Respondent for six repeated violations of the Act and its implementing regulations within a 36-month period.

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 six repeated violations in a 36-month period and so, Respondent is liable for a thirty consecutive day NTSO. *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, my December 18, 2017 Order, and my January 12, 2018 Order.

- c. I strike Respondent's October 6, 2017 Answer as a sanction pursuant to 21 C.F.R. § 17.35(c)(3).
- d. I find Respondent is in default.
- e. I assume the facts alleged in the Complaint to be true.
- f. I find the facts set forth in the Complaint establish liability under the relevant statute.
- g. I assess a 30 consecutive day No Tobacco Sale Order.

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