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

Center for Tobacco Products,
Complainant,

v.

GHA Enterprises Inc.
d/b/a Exxon 152,
Respondent.

FDA Docket No. FDA-2018-H-1655
CRD Docket No. T-18-2052

Decision No. TB3296

Date: November 30, 2018

# INITIAL DECISION AND DEFAULT JUDGMENT

Found:

1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (a)(2)(i) as charged in the Complaint;
2) Respondent committed three violations in a 24-month period as set forth hereinabove; and
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 |
| FDCA | Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) |
| FDA | Food and Drug Administration |
| HHS | Department of Health and Human Services |

[1] *See* 5 C.F.R. § 930.204.

| | |
|---|---|
| Respondent | GHA Enterprises Inc. d/b/a Exxon 152 |
| OSC | Order to Compel Discovery and Order to Show Cause to Respondent |
| 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 (Complainant or CTP) filed a Complaint on May 2, 2018, alleging that FDA documented three violations within a 24-month period.[3]

GHA Enterprises Inc. d/b/a Exxon 152 (Respondent or Exxon 152) was served with process on May 1, 2018, by United Parcel Service (UPS). On May 30, 2018, Robert D. Fingar and Michael J. Gabor noticed their appearances as counsel of record for Respondent. On the same day, Respondent, through counsel, filed an Answer.

On May 31, 2018, I issued a Pre-Hearing Order (PHO) establishing deadlines for parties' submissions, including a July 5, 2018 deadline to request documents from the opposing party. The PHO further set forth that, pursuant to 21 C.F.R. § 17.23(a), any

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

[3] CTP did not include prior violations that occurred outside of the relevant timeframe in the Complaint. *See* Complaint ¶ 1 n.1.

documents requested must be provided to the opposing party within 30 days of the request. The PHO also instructed that a party may move to compel or for sanctions if requested documents are not received within 30 days. Pursuant to my PHO, CTP served Respondent with a Request for Production of Documents on July 5, 2018. [4]

On August 3, 2018, Mr. Fingar filed a motion to withdraw Mr. Gabor as counsel of record for Respondent, asserting that Mr. Gabor is no longer employed with the firm, and as such, no longer represents Respondent and should be withdrawn as Respondent's counsel of record. On August 6, 2018, I granted the motion to withdraw ordering the appearance of Mr. Gabor to be withdrawn from this matter.

On August 23, 2018, CTP filed motions to compel discovery and extend deadlines indicating Respondent failed to respond to CTP's Request for Production of Documents. Respondent did not file a response to CTP's motions.

On September 27, 2018, I issued an Order to Compel Discovery and Order to Show Cause to Respondent (OSC). In the OSC, I granted CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's Request for Production of Documents by October 12, 2018. I further warned Respondent that "[f]ailure to comply will result in sanctions, which may include issuance of an Initial Decision and Default

[4] Respondent also timely served CTP with a Request for Production of Documents on July 2, 2018. Notably, Respondent's Request for Production of Documents was signed by Mr. Fingar. *See* Dkt. No. 7. On July 12, 2018, CTP filed a Motion for a Protective Order arguing disclosure is irrelevant, exempt under 21 C.F.R. Part 20, and/or otherwise privileged. Respondent failed to respond to CTP's Motion for Protective Order. On August 30, 2018, I issued an Order granting and denying in part CTP's Motion for Protective Order. In the Order, I also extended the simultaneous pre-hearing exchange deadlines until October 4, 2018.

Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." (Citation omitted). I also directed Respondent to show cause no later than October 12, 2018 why a default judgment should not be entered in favor of CTP.[5]

On November 8, 2018, CTP filed a Status Report and Motion for Default Judgment asserting Respondent failed to comply with my September 27, 2018 OSC. Because of Respondent's non-compliance, CTP argued that I should strike Respondent's May 30, 2018 Answer and issue a default judgment in the amount of $559.

To date, Respondent has not provided any response to my September 27, 2018 OSC as to why it failed to provide CTP with timely discovery nor has it responded to CTP's Motion for Default Judgment.

## III. STRIKING RESPONDENT'S ANSWER

Pursuant to 21 C.F.R. § 17.35(a)(1), I may sanction a party for failing to comply with an order, subpoena, rule, or procedure governing the proceeding. As outlined above, Respondent did not provide any response to CTP's Request for Production of Documents. *See* 21 C.F.R. § 17.23(a) (requiring document production within 30 days after receiving a request for production). Respondent also failed to comply with my May 31, 2018 PHO and my September 27, 2018 OSC.[6] Respondent, therefore, failed to

[5] My September 27, 2018 Order also extended the simultaneous pre-hearing exchange deadline to November 13, 2018, in case Respondent was able to show cause.

[6] In fact, neither Mr. Fingar nor Respondent has made any contact with this Court since the motion to withdraw Mr. Gabor as Respondent's counsel filed on August 3, 2018.

comply with my orders and procedures governing this proceeding. 21 C.F.R. § 17.35(a)(1). Accordingly, I find that sanctions are appropriate.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's noncompliance with my orders is sufficiently egregious to warrant striking Respondent's Answer. 21 C.F.R. § 17.35(c)(3). Accordingly, I am striking Respondent's Answer, assuming the facts alleged in CTP's Complaint to be true, and issuing this default decision without further proceeding. 21 C.F.R. § 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(a)(1) and (a)(2)(i).

## VI. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a)(1) and (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. My September 27, 2018 OSC instructed Respondent to comply with CTP's request for document production on or before October 12, 2018. I also directed Respondent to show cause no later than October 12, 2018, why a default judgment should not be entered in favor of CTP. Respondent failed to file any response or otherwise comply with my

September 27, 2018 OSC.

As a sanction, I hereby strike Respondent's Answer 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 owns an establishment, doing business under the name Exxon 152, located at 13695 Southwest 42nd Street, Miami, Florida 33175. 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 July 28, 2016, CTP issued a Warning Letter to Respondent, alleging that Respondent committed the following violation:

1. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a)(1).[7] Specifically, a person younger than 18 years of age was able to purchase a package of Pall Mall Menthol cigarettes on April 30, 2016, at approximately 10:29 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).

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

Further, during an inspection of Exxon 152 conducted on April 14, 2018, an FDA-commissioned inspector documented the following violations:

1. 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 cigarettes on April 14, 2018, at approximately 9:45 AM; and
2. 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 April 14, 2018, at approximately 9:45 AM.

B. Respondent's recitation of facts

I struck Respondent's Answer filed on May 30, 2018 from the record.

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

C. Violations

Under the current FDA policy, the violations described in the Complaint count as three violations for purposes of computing the civil money penalty (CMP) 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(a)(1) and (a)(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. § 387a-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 CMP 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 CMP 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 CMP, 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 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, 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), (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).[8]

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.

[8] 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 Tex. Dep't of Cmty. Affairs v. Burdine*, 450 U.S. 248, 254–55 (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).

## 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).

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 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 on April 30, 2016, and April 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. § 1140.14(a)(2)(i), on April 14, 2018, in that Respondent failed to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchaser is younger than 18 years of age.

The conduct set forth above on April 30, 2016, and April 14, 2018 counts as three violations under FDA policy for purposes of computing the CMP.

## 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 CTP, 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 three violations in a 24-month period and so, Respondent is liable for a CMP 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 May 31, 2018 Pre-Hearing Order and my September 27, 2018 Order to Compel Discovery and Order to Show Cause to Respondent.

c. Due to Respondent's noncompliance, I strike Respondent's Answer filed on May 30, 2018, 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 monetary penalty in the amount of $559.

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