DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

OFFICE OF ADMINISTRATIVE LAW JUDGES

Center for Tobacco Products, Complainant,

v.

Jomimi's, Inc., d/b/a Git-N-Go 2, Respondent

ORDER OF DEFAULT JUDGMENT
DOCKET NUMBER FDA-2015-H-3506

PROCEDURAL SUMMARY AND SUMMARY OF DECISION

The Complainant Center for Tobacco Products (CTP), U.S. Food and Drug Administration, U.S. Department of Health and Human Services, filed a complaint on October 7, 2015, seeking a civil monetary penalty in the amount of $500 from Respondent Jomimi's, Inc., d/b/a Git-N-Go2, for violating the federal Food, Drug, and Cosmetic Act. The CTP alleged three violations within a twenty-four-month period.

I initially dismissed the complaint with prejudice for two reasons: The Complainant did not demonstrate that the Respondent had actually received the complaint, and the Complainant refused to move for judgment. The Departmental Appeals Board ruled that my requiring proof of service and my requiring a motion for judgment were acceptable interpretations of the procedural rules, but it reversed the dismissal with prejudice and remanded the case to me for further proceedings. *See* DAB decision number 2695 of April 29, 2016.

I allowed the Complainant to "amend" its complaint and to seek to prove proper service on the Respondent. I directed the Complainant to include my remand order with its new Complaint. The remand order gave the Respondent a shorter amount of time to respond on the theory that the Respondent had, more than likely, been on notice of the pendency of this action since early October and would not be prejudiced by a shorter response time.

The time to respond has come and gone, and in fact the "standard" 30-day period, plus 5 for mailing (probably inapplicable in this case, as the document was delivered by a commercial service and a receipt has been added to the administrative record), has expired. 21 C.F.R. §§ 17.9, 17.30.

Having considered the CTP's allegation, the failure of Jomimi's to respond, and the applicable law and regulations, I conclude that the Respondent misbranded tobacco products on January 2, 2015, and June 7, 2015, and will be assessed a $500 civil penalty.

When a retailer such as Respondent is found to have "misbranded" a tobacco product in interstate commerce, it can be liable to pay a civil monetary penalty. 21 U.S.C. §§ 331, 333. A retailer facing such a penalty has a right, set out in statute, to a hearing under the Administrative Procedure Act. 21 U.S.C. § 333(f)(5)(A), (9). A retailer can forfeit its rights under the statute and regulations by failing to participate in the process, a failure known as "default". 21 C.F.R. § 17.11.

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).

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.

In the case of a default, an Administrative Law Judge (ALJ) must issue an initial decision within 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 (a)(2). *But see* 21 C.F.R. § 17.45 (initial decision must state the "appropriate penalty" and take into account aggravating and mitigating circumstances).

FINDINGS OF FACT AND CONCLUSIONS OF LAW

The Center's amended complaint, CE IX, alleges that the Respondent operates an establishment in Tampa, Florida, and that it receives tobacco products in interstate commerce. The complaint further alleges that the Respondent holds those tobacco products for sale. The interstate commerce basis for jurisdiction is presumed in cases involving tobacco products. 21 U.S.C. § 379a.

The Respondent in this case received the amended complaint, on June 17, 2016. CE X. I am satisfied by the filings after the remand that the Respondent has received the complaint and has failed to make a substantive answer, to request an extension, or to demand a hearing. The Respondent is therefore in default.

The Center's complaint alleges that on January 2, 2015, the Respondent sold a package of Maverick Box 100's cigarettes to a "minor," later more fully described as a person under the age of 18, around 4:02 p.m. The complaint further alleges that the purchaser was not asked for photographic identification. The Center also alleges that, on June 7, 2015, the Respondent sold a package of Pall Mall Orange cigarettes to a minor around 12:42 p.m., and that the Respondent again failed to demand photographic identification of the purchaser.

Accepting those allegations as true, 21 C.F.R. § 17.11, I conclude that the Respondent misbranded those tobacco products and in the process, consistent with *CTP v. Orton Motor*, DAB decision number 2717 of June 30, 2016, committed four infractions of the Secretary's regulations. Both sales violated both 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1).

The Respondent has not offered any evidence in extenuation of the infractions or in mitigation of the proposed penalty because the Respondent is in default. By regulation, therefore, I must assess the penalty of $500 because the Complainant has requested that amount, not the higher amount of $2000 authorized by the regulations.

PROCEDURAL INSTRUCTIONS

This initial decision becomes final and binding on the Parties 30 days after it is issued. 21 C.F.R. § 17.11(b); *see also* 21 C.F.R. § 17.30. Before that 30-day period elapses, the defaulting Respondent may move me to reopen this decision and permit it to file an answer. 21 C.F.R. § 17.11(c). Either Party may appeal this decision to the Departmental Appeals Board (DAB) within 30 days after this initial decision is issued. 21 C.F.R. § 17.47. The Parties are directed to the cited regulations, available at www.gpo.gov, for specific requirements. Further information on filing an appeal is available at the DAB's website, www.hhs.gov/dab/divisions/appellate, or by telephone at (202) 565-0208.

Lewis T. Booker Jr -S

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LEWIS T. BOOKER, JR.
U.S. Administrative Law Judge

Attachments (single page):

Service List

Exhibit List (all exhibits were previously served on both the Complainant and the Respondent; they are not attached to this initial decision)

SERVICE LIST

Respondent (via certified mail # 7013 1710 0002 2126 7237):

Jomimi's, Inc., d/b/a Git-N-Go 2/Get-N-Go
ATTN: Site Manager
7802 Rideout Road, A
Tampa, FL 33619

Complainant (hand-delivery, FDMS, e-mail):

Michelle Svonkin, Esq.
Attorney for Complainant CTP, FDA
White Oak 32, Room 4308
10903 New Hampshire Avenue
Silver Spring, MD 20993

COURT EXHIBIT (CE) LIST

CE	DESCRIPTION
I	Complaint of October 7, 2015
II	"Proof of Service" of October 8, 2015
III	Procedural Order to CTP of February 3, 2016
IV	"Signed Proof of Service" of February 4, 2016
V	Order to Complainant to Show Cause, March 9, 2016
VI	Response to OSC, March 16, 2016.
VII	Dismissal with Prejudice, March 22, 2016
VIII	Order on Remand, May 16, 2016
IX	Amended Complaint, June 10, 2016
X	Notice of Filing, June 17, 2016