U.S. FOOD & DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF ADMINISTRATIVE LAW JUDGES

Center for Tobacco Products,
Complainant,

v.

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

ORDER DISMISSING COMPLAINT

DOCKET NUMBER FDA-2015-H-3506

In my Order to Show Cause dated March 9, 2016, I put the Complainant on notice (a) that the proof of service was insufficient, and that further proof was required, (b) that responses to the Order were to be in the form of a pleading, not in the ministerial act of filing a document in a repository, (c) that I was not part of the "enforcement mechanism" of the Food and Drug Administration, and therefore would not act absent a motion to do so, (d) that satisfactory proof of service must be filed by March 16, 2016, (e) that a motion for default judgment must be made no later than March 21, 2016, and (f) that failure to comply with the Order would result in a dismissal of the complaint with prejudice. *See* 21 C.F.R. § 17.35.

In its response to the Order to Show Cause, dated March 16, 2016, the Complainant has said it has no intention to comply with the order, either as far as additional evidence of service is concerned or as far as moving for a judgment is concerned. The Complainant argues that the Administrative Law Judge (ALJ) must defer to its interpretation of regulations, citing *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994). The Complainant fails to distinguish between substantive rules, such as the Medicare reimbursement rules at issue in *Thomas Jefferson University*, and procedural rules, such as those involved in imposing civil monetary penalties under Part 17 of title 21, Code of Federal Regulations.

The Complainant has deliberately flouted a legal procedural order of the ALJ. It knew when it did so that there would be consequences, and it knew what those consequences were likely to be. Accordingly, the Complaint of October 7, 2015, alleging

misbranding of a tobacco product on June 7, 2015, is dismissed with prejudice.

SERVICE OF A COMPLAINT

The Complainant avers that it created and served a complaint on the Respondent alleging misbranding of tobacco products. The Complainant has produced a "tracking document" from a commercial shipping concern that shows that a parcel, bearing an identification number, was delivered to a city and state on a date certain. In response to an earlier Procedural Order, the Complainant supplemented that "tracking document" with a "delivery notification" which, while providing more detail about where and to whom the package was delivered, still provides no information at all about the contents of the package. The Complainant supplied the "delivery notification" not through a formal responsive pleading, but rather by placing it in a repository of electronic files.

The Complainant apparently rests on those actions to prove that the complaint was properly served, as it provides no other *evidence* (the allegations in its response to show cause being just that, *allegations*), such as an affidavit from the person who actually placed the document in the shipping envelope, or a photocopy of the complaint with the tracking number imprinted on it, that the complaint was placed in the hands of a commercial carrier for service. Indeed, the complaint itself shows no indication of shipping address or shipping information.

In this regard as well, I note that the complaint was signed by a person identified as "Attorney for Complainant," that the "inquiry" that surfaced the "delivery notification" was made by a different person, at a different address (one in Fairfax, Virginia, as opposed to the Complainant's address in Silver Spring, Maryland, with no indication to whom the "shipper number" noted on the form is attached), and that the assertions in the Complainant's Response to the Order to Show Cause were made by yet a different "Attorney for Complainant".

While the Complainant is correct that U.S. mail and commercial courier (United Parcel Service, in this case) services are authorized means of service in these cases, that argument answers only the "how" of service. What the Complainant has failed to answer is the "what": what was in the parcel? The statements in the Complainant's response to the Order to Show Cause are not evidence; they are assertions by an advocate. There is simply no evidence that it was the complaint

against the Respondent, and not a collection of recipes, drawings, newspaper clippings, or any other printed matter, that went into the envelope handled by the commercial courier. Logically, of course, it was the complaint that went into the envelope, but the Complainant has not pointed to any presumption, or to any evidence, entitling it to that inference.

The Complainant's attention is directed to the "proof of service" rule, which provides that proof of service must include "the name and address of the person on whom *the complaint* was served." 17 C.F.R. § 17.7(b)(emphasis supplied). Absent some evidence that the "parcel" that was left at "your customer's front desk" (as the delivery notification styles it) contained *the complaint*, the Complainant has failed to make the showing necessary for a determination of default. *See also* 60 Fed. Reg. 38617 (July 27, 1995), FDA Response to Comment 41.

The Complainant argues in its Response that it should be entitled to a presumption of administrative or ministerial regularity, citing *Butler v. Principi*, 244 F.3d 1337, 1340 (Fed. Cir. 2001). In contrast to the facts of *Butler*, however, there is nothing in the record tying the specific complaint in this case to the ministerial actions that are supposed to have put it in the hands of the Respondent: no contemporaneous file entries, no instructions to subordinates, none of that. Interestingly, and perhaps ironically, the Complainant's Response to the Order to Show Cause demonstrates an ability to comply with the rules regarding service.

These considerations are not insubstantial. In the case of a default judgment, the assumption is that the Respondent has been notified of a particular claim against him and has been given an opportunity to state his side of the case. When or if the Respondent fails to present his side of the case, he has forfeited the opportunity and the case may proceed to judgment absent his dissenting voice. When a default is properly identified and a default judgment is properly entered, the Respondent's rights are appropriately curtailed. *See* 21 C.F.R. § 17.11(c). *See generally H.F. Livermore Corp. v. Aktiengesellschaft Gebruder Loepfe*, 432 F.2d 689, 691 (D.C. Cir. 1970)(per curiam). As the party seeking to proceed to a default judgment, the Complainant must satisfy the ALJ that the table has been correctly set. Here, the Complainant has not done so.

FAILURE TO PROSECUTE

Even assuming that service was proper, the Complainant further refuses to move for a default judgment in this case, despite having been admonished to do so if it believed that the facts warranted such a judgment. The Rule requiring a motion for a decision or ruling, 21 C.F.R. § 17.32, serves a salutary purpose, namely, to distinguish between the Complainant's role as prosecutor and the ALJ's role as independent arbiter of fact and law. It is, as well, a statement by the Secretary that due process contemplates such an action by a Party. *See also* 21 U.S.C. § 333(f)(5).

This distinction is particularly important in assuring the regulated entities that there is an independent assessment of every request for a penalty. If an ALJ were expected to be a "self-starter," searching through files and deciding cases that appeared to be ripe, the ALJ would be nothing more than an extension of the Complainant's investigation and enforcement mechanism. If this were in fact the intended application of the procedural rules, there would be no need for an ALJ to be involved in the process; all that would be necessary would be to send a bill to a delinquent Respondent, a task better suited to a mere algorithm.

The Complainant claims that a motion is not needed, because in the case of a default "the presiding officer shall the facts alleged in the complaint to be true," and shall, if liability under the relevant statute be established, impose "the maximum amount of penalties provided for by law for the violations alleged; or the amount asked for in the complaint, whichever is smaller." 21 C.F.R. § 17.11. The Complainant argues, citing use of the mandatory term "shall," that this rule requires the ALJ to act once the default occurs, and apparently on his own initiative. The Complainant misunderstands the provisions of this particular rule, however.

Rule 17.11 serves two purposes. First, it tells all that the Complainant is entitled to a presumption, a legal shortcut to establishing facts, in the case of a default. The Complainant need not put on any evidence to support its allegations:

> "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, the rule limits the ALJ's discretion with respect to penalty: the ALJ may not impose any penalty greater than those specified in the regulation (the maximum amount or the requested amount, whichever is lower) lest the Respondent's due process rights (especially notice, whether legal or actual, of the proposed penalty) be affected; likewise the rule limits the ALJ's discretion to tailor a penalty (this is what "shall impose" means), as might be the case under other circumstances. 21 C.F.R. § 17.45(b)(3).

CONCLUSION

I recognize that dismissal with prejudice is a drastic remedy, just as a default judgment is a drastic remedy. In this case, however, given the Complainant's inability to provide adequate proof of service of the complaint, and given its willful refusal to move for the ruling to which it believes itself entitled, the sanction threatened in the Order to Show Cause is appropriate. This complaint is dismissed with prejudice.

So Ordered.

Lewis T. Booker

LEWIS T. BOOKER, JR.
United States Administrative Law Judge

22 MARCH 2016

SERVICE LIST

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

Michele Svonkin, Esq.
Center for Tobacco Products, FDA
White Oak 32, Room 4308
10903 New Hampshire Avenue
Silver Spring, MD 20993

Respondent (via U.S. Mail):

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