

UNITED STATES OF AMERICA
BEFORE THE ADMINISTRATIVE LAW JUDGE
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Tobacco Products
Complainant

v.

T and M United Corporation d/b/a BP Shop
Respondent

FDA Docket No. FDA-2015-H-3507

ORDER ON REMAND

This Order is issued pursuant to the Remand to Administrative Law Judge (RALJ).¹

Compliance with this Order shall be by filing a proper Proof of Service (POS) under the parameters of 21 C.F.R. § 17.7, by some other pleading or a procedure of Complainant's choosing consistent with 21 C.F.R Part 17 and the RALJ. Prosecution of this cause of action is within the discretion of Complainant. We leave the mechanics of compliance with rule 21 C.F.R Part 17 to the discretion of the Complainant.

Filing of a proper POS will be considered full compliance with this Order and no additional pleading need be filed if a proper POS is filed. If Complainant needs to re-serve the original complaint to perfect service, it may do so without the need to file a motion to amend the complaint.

Once Complainant demonstrates proper service, the burden will shift to Respondent to overcome the presumption² in favor of valid service of service by Complainant.

¹ Docket No. A-16-84, Decision No. 2705, May 24, 2016.

²The 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).

Again, we leave the mechanism of compliance with the rules to the discretion of the Complainant.

If Complainant fails to submit a POS consistent with 21 C.F.R. Part 17, we will allow Complainant to supplement their submission to demonstrate how, in particular, the complaint was properly served in the first instance. This matter will not proceed until proper service has been demonstrated. If Complainant refuses to comply entirely, this matter may be dismissed.

Upon demonstration of proper service, if the Complainant seeks judgment by default it shall do so by filing a motion (21 C.F.R. §17.32). If Complainant, after demonstrating proper service of process, chooses not to file a Motion for Default, we will set this matter for hearing.

We reiterate, filing of a proper Proof of Service as set forth above will be considered compliance with this Order and a further pleading would not be required.

WHEREFORE, Complainant be and is hereby ORDERED as follows:

Demonstrate proper service of the complaint by proffering evidence demonstrating that the UPS delivery, or other manner of service, related to the mailing of the complaint consistent with 21 C.F.R. §17.7

Richard C. Goodwin
U.S. Administrative Law Judge

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 (1998) at 1440.

SERVICE LIST

Respondent, COPY via postage prepaid, First Class Mail:

T AND M UNITED CORPORATION D/B/A BP SHOP
Site Manager
3230 N HIGHWAY 1
COCOA FL 32926

Complainant (via Federal Docket Management System and/or email):

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