Department of Health and Human Services
Food and Drug Administration
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 OF DISMISSAL

I. Introduction

The Center for Tobacco Products (CTP or Complainant), Food and Drug Administration (FDA), United States Department of Health and Human Services (HHS) filed a complaint dated October 7, 2015 seeking a civil money penalty (CMP) from T and M United Corporation d/b/a BP Shop, (Respondent or T and M) for violating FDA's tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (Act) 21 U.S.C. § 387f(d).

The complaint identified the Respondent as T and M United Corporation d/b/a BP Shop and alleged Respondent owned an establishment, doing business under the name BP Shop, located at 3230 North Highway 1, Cocoa, FL 32926.

On October 9, 2015, Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) was filed in FDMS. Information on the POS stated that it was proof of delivery for a shipment with a tracking number 1Z6Y03R02492104652, shipped on 10/07/2015, delivered on 10/08/2015, 9:35 A.M., Delivered To: COCOA, FL, US, Signed By: ELDRIDGE and Left At: Receiver. There was no proof of service attached to the document (21 C.F.R. § 17.7)

On February 11, 2016 a Document #0004 titled "Signed POS for T and M United Corporation d/b/a BP Shop" (POD) was filed in FDMS. The document was titled "Delivery Notification". Information on the form implied an inquiry was received from "SAMANTHA ALBRIGHT CTP\HQ\DSI, 12150 MONUMENT DR, RM 100, FAIRFAX VA 22033." Additional information on the form indicated a SHIPMENT was sent to "T AND M UNITED CORPORATION, D/B/A BP SHOP, 3230 N HIGHWAY 1, COCOA FL 32926", with Shipper Number 6Y03R0 and Tracking Identification Number 1Z6Y03R02492104652. The form stated "According to our records 1 parcel was delivered on 10/08/15 at 9:35 A.M. The shipment was signed for by ELDRIDGE..." There was no proof of service attached to the document (21 C.F.R. § 17.7)

Our Procedural Order (PO) was filed February 12, 2016 and is incorporated herein by reference as if fully set forth. In our order we stated:

"To date, no document has been filed with the Office of Administrative Law Judges (OALJ) and/or with FDMS alleging service of the complaint was effected in accordance with 21 C.F.R. § 17.7.

FDMS contains a UPS 'Proof of Delivery' dated 10/08/2015 with a tracking number 1Z6Y03R02492104652 indicating "something" was delivered on 10/08/2015 to Cocoa, FL signed by "ELDRIDGE"'. This document does not set forth all the necessary identifying information required by 21 C.F.R. Part 17 to demonstrate proof of service of the complaint. Nor is there any information in the administrative record that links the proof of service to the complaint."

The PO did not include any deadline for compliance and CTP filed no pleading in response to our Procedural Order.

Our PO also observed no application to the administrative law judge had been made requesting relief pursuant to (21 C.F.R. § 17.32). We commented further "If CTP believes that a default judgment is warranted against a properly served Respondent, it may file an appropriate motion".

An Order captioned "Procedural Order (OSC) was filed on March 10, 2016, and is incorporated herein by reference as if fully set forth herein. Our OSC reiterated that:

…FDMS contains a UPS 'Proof of Delivery' filed 10/09/2015 with a tracking number 1Z6Y03R02492104652 indicating "something" was delivered on 10/08/2015 to Cocoa, FL signed by "ELDRIDGE". On February 11, 2016, a document captioned "Delivery Notification" was filed in FDMS alleging a 'SHIPMENT' was delivered to T AND M UNITED CORPORATION, D/B/A BP SHOP, 3230 N HIGHWAY 1, COCOA FL 32926; Shipper Number 6Y03R0, Tracking Identification Number 1Z6Y03R02492104652; containing 1 parcel which was delivered on 10/08/15 at 9:35 A.M. The shipment was signed for by ELDRIDGE.

Neither of these documents sets forth all the necessary identifying information required by 21 C.F.R. Part 17 to demonstrate proof of service of the complaint. Nor is there any information in the administrative record that links the proof of service to the complaint...

… There is no evidence (for example, an authenticated and properly dated certificate of service; an affidavit attesting to placing a specific complaint in a specific mailing envelope; a certified receipt number on an individual complaint) linking a specific complaint to a specific respondent. The Complainant may not rely upon any sort of presumption of administrative regularity in this regard, as the Respondent's due process rights hang in the balance.

"Corporation" attached to the name of the Respondent suggests that Respondent is a corporation. Service of a complaint on a corporate entity may be

made by serving "…an officer or managing or general agent in the case of a corporation or unincorporated business…" (21 C.F.R. § 17.7 (a))

There is nothing in the record identifying relationship of ELDRIDGE to the Respondent.

There is no indication in any of CTP's pleading or filings that the complaint was delivered to Respondent, because the contents of "the parcel" and/or 'shipment' were not described.

We spelled out further deficiencies in the administrative record, and stated:

If the Complainant believes that it has demonstrated the requisite proper service, it shall move for a default judgment, and it shall do so no later than Monday, March 21, 2016. Failure to do so will be construed as an abandonment of the complaint and will result in a dismissal with prejudice. 21 C.F.R. § 17.35. The Respondent will be served with a copy of the motion for default judgment and may respond to the motion by Monday, March 28, 2016. 21 C.F.R. § 17.32.

Failure to comply with this ORDER in any particular will result in a dismissal with prejudice. 21 C.F.R. § 17.35.

Complainant filed a Response to Order to Show Cause (CROSC) on March 16, 2016. The Certificate of Service attached to the CROSC failed to identify the "document" to which it referred. The Certificate of Service should name the pleading served, the time and manner of service and name the individual providing the certification.

Complainant argued service was effected consistent with the controlling regulations and there was no requirement that Complainant file a motion seeking default. Complainant argued:

"…Because the complaint was properly served, the time period for filing an answer has expired, and the facts alleged in the complaint establish liability under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"), the ALJ is required under the controlling regulation to issue an initial decision of default in this matter. Because the facts alleged in the complaint support a civil money penalty of $250, as requested by CTP, the ALJ's initial decision should impose the requested civil money penalty."

Complainant further stated:

"Because the controlling regulations do not require a party to file a motion seeking default, CTP does not intend to file a motion seeking default in this matter." (Fn 1, CROSC)

Our OSC directed the Complainant to demonstrate that it had complied with the service requirements of 21 C.F.R. § 17.7. As of March 16, 2016, Complainant failed to show it had

complied with service of process requirements.

Complainant failed to move for default judgment or otherwise request relief aside from the initial prayer for relief in the complaint in spite of our reiteration of language in the rule stating the presiding officer may not provide relief except upon motion by a party, and the presiding officer has neither the authority nor the duty to rule sua sponte. 21 C.F.R. § 17.32(a).

Complainant failed to demonstrate that Respondent was served and/or properly served or otherwise comply with the regulation (21 C.F.R. § 17.7).

Complainant failed to move for Default Judgment stating that "…Because the controlling regulations do not require a party to file a motion seeking default, CTP does not intend to file a motion seeking default in this matter…"

Complainant failed to comply with our OSC.

The presiding officer may impose sanctions on a party for failure to comply with an order or prosecute an action. 21 C.F.R. § 17.35(a)(1). We will DISMISS, the civil money complaint dated October 7, 2015, for failure to demonstrate Service of Process, for failure to Move for Default Judgment, for failure to comply with our OSC and by Complainant's representation that CTP does not intend to file a motion seeking default in this matter, thereby abandoning prosecution in this matter (21 C.F.R. § 17.35).

II. Analysis

A. Complaint

Complainant identified the Respondent as "T and M United Corporation d/b/a BP Shop". The complaint provided no information about the nature of Respondent, i.e., whether Respondent was an individual, sole proprietorship, partnership, Limited Liability Corporation, incorporated or unincorporated entity. The complaint provided no information whether or where Respondent maintained a headquarters or main office location.

"Corporation" was attached to the name of the Respondent suggesting the Respondent may be an incorporated entity. But neither the complaint nor the record provide further information about the Respondent other than "Respondent owns an establishment, doing business under the name BP Shop, located at 3230 North Highway 1, Cocoa, FL 32926."

The rules state: "The Center with principal jurisdiction over the matter involved shall begin all administrative civil money penalty actions by serving on the respondent(s) a complaint." (21 C.F.R. § 17.5). We cannot determine whether service of a complaint has been made consistent with the applicable rule (21 C.F.R. § 17.7) without knowing the nature of the Respondent's business.

B. Service of Process

21 C.F.R. § 17.7 sets forth the manner of service of a complaint:

a) Service of a complaint may be made by:
(1) Certified or registered mail or similar mail delivery service with a return receipt record reflecting receipt; or
(2) Delivery in person to:
(i) An individual respondent; or
(ii) An officer or managing or general agent in the case of a corporation or unincorporated business.
(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:
(1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;
(2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or
(3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

1. Respondent's identity

Complainant provided no information about the identity of the Respondent other Respondent owned an establishment, doing business under the name BP Shop, located at 3230 North Highway 1, Cocoa, FL 32926. The administrative record provided no information about whether the Respondent was an individual, sole proprietorship, partnership, Limited Liability Corporation, incorporated or unincorporated entity.

Without knowledge of the Respondent's identify, we cannot determine whether or which provision of 21 C.F.R § 17.7 applies in this case.

2. Address

Complainant alleged the Respondent operated a business at 3230 North Highway 1, Cocoa, FL 32926.

The POS document in FDMS titled "Proof of Service for T and M United Corporation d/b/a BP Shop" indicated a "shipment" was delivered to "COCOA, FL, US" and signed for by Eldridge.

The POD Document in FDMS titled "Signed POS for T and M United Corporation d/b/a BP Shop" indicated a 'delivery', 'shipment' and/or "parcel' was delivered to T and M United Corporation D/B/A BP Shop, 3230 N Highway 1, Cocoa FL 32926 and signed for by Eldridge. The address in the POD was consistent with the address in the complaint.

3. Certificate of Service

The POS and POD were uploaded to FDMS. There was no physical file for the court to examine.

21 C.F.R. § 17.7 provides in pertinent part:

> (b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:
> (1) Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery;
> (2) A United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or
> (3) Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent.

There was no proof of service "…stating the name and address of the person on whom the complaint was served, and the manner and date of service…" (21 C.F.R. § 17.7 (b)) filed with either the POS or the POD filed in FDMS.

There was no "…Affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery…" filed with either the POS or POD (21 C.F.R. § 17.7 (b)(1)).

There was no "…United States Postal Service or similar mail delivery service return receipt record reflecting receipt…" filed with either the POS or POD (21 C.F.R. § 17.7 (b)(2)).

There was no "…Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent…" filed with either the POS or POD (21 C.F.R. § 17.7 (b)(3)).

There was no information in the record explaining the identity of "Eldridge" other than the explanation in the POD that "According to our records 1 parcel was delivered on 10/08/15 at 9:35 A.M. The shipment was signed for by ELDRIDGE". An unreadable signature appears thereafter.

There is nothing in the record to indicate whether or not Eldridge was authorized to accept service on behalf of the Respondent.

4. The inquiry

The complaint itself shows no indication of the Respondent's home address, headquarters, shipping address or shipping information. In this regard as well, I note that the complaint was signed by a person identified as "Attorney for the Complainant," with an address of record of Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

Without explanation in the record, the POD (FDMS Document #0004) apparently responds to an "inquiry" made by a different person, at a different address - 12150 Monument Drive, Room 100, Fairfax, VA 22033 - 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 nor why the addresses are in different states.

Assertions in the Complainant's Response to the Order to Show Cause were made by yet a different counsel of record at Center for Tobacco Products, United States Food and Drug, Administration, White Oak 32, Room 4308, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002.

5. What?

While the Complainant was correct that U.S. mail and commercial services were authorized means of service in these cases, that argument answers only the "how" of service. What the Complainant failed to answer was the "what"; what was in the parcel, shipment and/or delivery? Complaint argued "…Because the complaint was properly served…" There was nothing in the record of evidence to support the argument that a **complaint** was served, let alone properly served.

Statements in the Complainant's response to the OSC were not evidence; they were assertions/arguments by an advocate. There was simply no evidence from the Complainant that it served the complaint against the Respondent on anyone or any entity. There was no evidence in the record describing what was contained in the shipment, delivery or parcel. Based on the evidence in the record we cannot determine what, if anything, was delivered; or whether the shipment, delivery or parcel contained a collection of recipes, drawings, newspaper clippings, or any other printed or non-printed matter handled by the commercial courier. Based on the evidence in the record, the shipment, delivery or parcel may have been empty.

The Complainant's attention was 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" delivered to "your customer" (as the delivery receipt 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.

Complainant's argument that "There is simply no basis to doubt that CTP's employees placed the complaint and cover letter that it filed in this case into the UPS parcel that was delivered to the Respondent" was unsupported. There was NO evidence in the record to support that argument.

Complainant confused method with results. The Complainant was correct that U.S. mail and commercial services were authorized means of service in these cases.

There was no information or evidence in the administrative record that linked the proof of service to any complaint.

Complainant failed to show by evidence, affidavit, or proof of service consistent with the rules that anything was actually delivered at the addresses set forth above.

6. Who?

The POD in the record indicated the parcel/delivery/shipment was signed by "Eldridge". The POS indicates a shipment was "Left at: Receiver". There was no explanation in the record on the identity of "Eldridge", whether or not he/she was an employee of Respondent and/or whether "Eldridge" was or was not authorized to accept service on process on behalf of Respondent. There is nothing in the record explaining what "Receiver" may be.

C. Motion for Default:

Respondent was in default only if it had been properly served as provided in 21 C.F.R. § 17.7. Service of process herein was NOT accomplished in accordance with 21 C.F.R. § 17. The documents in FDMS and referred to by CTP do not set forth all the necessary identifying information required by 21 C.F.R. Part 17 to establish a prima facie showing of proper service of process of the complaint.

1. 21 C.F.R. § 17.7

Complainant argued "A motion seeking dismissal was not required under the controlling regulations, and therefore, the failure to file such motion provides no grounds for dismissal" citing 21 C.F.R. § 17.11. Complainant argued the rule states:

> If the respondent does not file an answer within the time prescribed in § 17.9 and if service has been effected as provided in § 17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing [a civil money penalty].

Complainant misstates the rule. The rule in its entirety states:

21 C.F.R. § 17.11 Default upon failure to file an answer.

(a) If the respondent does not file an answer within the time prescribed in 17.9 and if service has been effected as provided in 17.7, the presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

(1) The maximum amount of penalties provided for by law for the violations alleged; or

(2) The amount asked for in the complaint, whichever amount is smaller.

(b) Except as otherwise provided in this section, by failing to file a timely answer, the respondent waives any right to a hearing and to contest the amount of the penalties and

assessments imposed under paragraph (a) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(c) If, before such a decision becomes final, the respondent files a motion seeking to reopen on the grounds that extraordinary circumstances prevented the respondent from filing an answer, the initial decision shall be stayed pending a decision on the motion.

(d) If, on such motion, the respondent can demonstrate extraordinary circumstances excusing the failure to file an answer in a timely manner, the presiding officer may withdraw the decision under paragraph (a) of this section, if such a decision has been issued, and shall grant the respondent an opportunity to answer the complaint as provided in 17.9(a).

(e) If the presiding officer decides that the respondent's failure to file an answer in a timely manner is not excused, he or she shall affirm the decision under paragraph (a) of this section, and the decision shall become final and binding upon the parties 30 days after the presiding officer issues the decision on the respondent's motion filed under paragraph (c) of this section.

Complainant argued the provisions of 21 C.F.R. § 17.11 excuse it from compliance with 21 C.F.R. §17.32.

2. 21 C.F.R. § 17.32 Motions, states in its entirety:

(a) **Any application** to the presiding officer for an order or ruling **shall** be by motion. Motions **shall** state the relief sought, the authority relied upon, and the facts alleged, and **shall** be filed with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, delivered to the presiding officer, and served on all other parties.

(b) **Except** for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The presiding officer may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the presiding officer, any party may file a response to such motion.

(d) The presiding officer may not grant a written motion before the time for filing responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response. [Emphasis added]

3. Comparison of 21 C.F.R. §17.11 and 21 C.F.R. § 17.32.

Rules 21 C.F.R. § 17.11 and 21 C.F.R. § 17.32 are not exclusive. We cannot consider one rule over another; all rules must be read in context, completely and collectively. What is

significant in the interpretation of rules 21 C.F.R. § 17.11 and 21 C.F.R § 17.32 is what the rules do NOT say:

> 17.11 does NOT say "…without the necessity of filing a motion under 17.32, the presiding officer shall issue an initial decision within 30 days of the time the answer was due…"
>
> 17.32 does NOT say "…with the exception of initial decisions under 17.11 any application to the presiding officer for an order or ruling shall be by motion…"

Complainant's argument takes a selected portion of 17.11 out of context with the remainder of the language of the rule. 17.11 provides for presumptions in case of a default and provides boundaries on an administrative law judge's discretion as to the amount of penalty to impose. It does not excuse a party from compliance with 17.32.

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, 17.11 limits the ALJ's discretion with respect to penalty. The ALJ may not impose any penalty greater than those specified by the regulation lest the Respondent's due process rights be affected; likewise the rule limits the ALJ's discretion to tailor a penalty (this is what "shall impose" means), as would be the case under other circumstances. 21 C.F.R. § 17.45(b)(3).

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. In an adversarial system, the role of a judge is not to conduct a factual or legal investigation by himself or herself, but rather to decide based on facts and arguments adduced by the parties in a case. An adversarial system relies on the parties to raise significant issues and present them to the court for adjudication. *See Sanchez-Llamas v. Oregon*, 548 U.S. 331, 356-57, 126 S.Ct. 2669, 165 L.Ed.2d 557 (2006). *See also* 21 U.S.C. § 333(f)(5).

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.

Complainant argued "shall" creates a mandatory duty on the ALJ to issue an initial decision pursuant to CTP's interpretation on 21 C.F.R. § 17.11, which is taken out of context. Complainant failed to read 21 C.F.R. § 17.11 in its entirety and/or in context with other provisions of the procedural rules.

Complainant then argued:

> nowhere in 21 C.F.R. § 17.11(a) does it state that a party is required to file a motion seeking default. Because there is a regulation directly addressing default, the separate provision requiring parties to file motions with the presiding officer seeking an order or ruling, 21 C.F.R. § 17.32, is inapplicable in the default context.

We disagree.

First, Complainant took a portion of 21 C.F.R § 17.11 out of context to support its argument.

Second, Complainant's position was in opposition to the clear language of 21 C.F.R § 17.11 and 21 C.F.R § 17.32. 21 C.F.R. § 17.32 clearly states: "**Any** application to the presiding officer for an order or ruling **shall** be by motion" (21 C.F.R. §17.32 (A) (Emphasis added). 21 C.F.R. § 17.32 does NOT say 'except for situations where the respondent does not file an answer any application to the presiding office for an order or ruling shall be by motion". Neither 21 C.F.R. § 17.11 nor 21 C.F.R. § 17.32 excuses a party from filing a motion in the case where the Respondent may be in default. A clear reading of the rules is that a party SHALL file a motion with the presiding officer to obtain relief. "The plain language of a statute is strong evidence of Congress's intent" (*Port Authority of New York and New Jersey v. Department of Transp*., 479 F.3d 21,31 (D.C. Cir. 2007). Again, Complainant failed to consider the entirety of the rules and took only a portion of the rule out of context to support its position.

Complainant also argued that the ALJ should give deference to its interpretation of FDA's regulations. Although courts ordinarily grant deference to an agency's interpretation of its regulations, such deference is not appropriate where the interpretation is clearly erroneous or plainly inconsistent with the regulations, or when the proffered interpretation appears to be a mere litigating position of the agency. *See Christopher v. SmithKline Beecham Corp.,* 132 S.Ct. 2156, 2166, 183 L.Ed.2d 153 (2012). Complainant's position is not consistent with the text of 21 C.F.R. §§ 17.11 and 17.32 when these provisions are read together, as explained *supra*. Moreover, Complainant does not point to any guidance or other FDA pronouncement where the agency adopted the interpretations of the Part 17 rules that Complainant is advancing in its CROSC. Nor did any of the Departmental Appeals Board cases that Complainant cited

explicitly address, let alone analyze, the specific issues presented here. Complainant appears to be taking its positions as a matter of convenience for litigating its civil money penalty cases.

Under the Administrative Procedure Act (APA), a unitary agency such as FDA is required to split enforcement and adjudication between separate personnel. *See* 5 U.S.C. 554(d) (2012); *Martin v. Occupational Safety & Health Review Comm'n*, 499 U.S. 144, 151, 111 S.Ct. 1171, 113 L.Ed.2d 117 (1991). In such unitary agencies, adjudication is a vehicle not only for fact-finding, but also lawmaking by interpretation. *Martin*, 499 U.S. at 154. The adjudicator's decision is the agency's decision. *See Ingalls Shipbuilding Inc. v. Director, OWCP*, 519 U.S. 248, 267-69, 117 S.Ct. 796, 136 L.Ed.2d 736 (1997). Therefore, to the extent that an ALJ presiding over a Part 17 case applies FDA's laws and regulations, as written, to make a decision in that case, the ALJ's interpretation of those laws and regulations, as the agency's adjudicator, would be entitled to deference by a reviewing court under the very authorities that the Complainant cites.

Both 21 C.F.R. § 17.11 and 21 C.F.R. § 17.32 use the word "shall" as a mandatory duty. Rules 21 C.F.R. § 17.11 and 21 C.F.R. § 17.32 are consistent, not mutually exclusive. It is within our authority as ALJs to interpret the rules to conclude that 21 C.F.R. § 17.32 requires a Motion for Default be filed before the court will consider the issue and that a party shall file a motion to obtain relief from the presiding officer. That interpretation is within our authority as ALJs and consistent with our obligations under the APA and agency rules. (5 U.S.C.A. § 3105; 5 U.S.C.A. § 556; *Butz v. Economou*, 438 U.S. 478, 513; 98 S.Ct. 2894; 57 L.Ed.2d 895 (1978)); (*Federal Maritime Com'n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002)); 21. C.F.R. § 17.19). (*Port Authority of New York and New Jersey*, at 37)

4. Service of Process

Complainant failed to comply with the clear language of its own regulations with respect to service of process. There was no proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service which would comply with any of the provisions of 21 C.F.R. Part 17. The documentation referenced by Complainant did not set forth all the necessary identifying information required by 21 C.F.R. Part 17 to demonstrate proof of service of the complaint.

Nor was there any information in the administrative record that linked the proof of service to the complaint.

> The term "service" has been defined as "the exhibition or delivery of a writ, summons ... notice, order... to a person who is thereby officially notified of some action or proceeding in which he is concerned, and is thereby advised or warned of some action or step which he is commanded to take or to forbear." Black's Law Dictionary 1368 (6th ed. rev. 1990). Specifically, our supreme court has stated that "service of notice" has a definite meaning, and unless otherwise provided by law means "personal service of the individual in such a way that the party who makes service may be in a position to make due proof thereof to the court. (*Hendricks County Bank & Trust Co. v. Guthrie Bldg. Materials, Inc.*, 663 N.E.2d 1180, 1185 (1996)). (Citations omitted). It is inherent in the concept of

> "service" that service of notice upon a person or entity imposes legal obligations and consequences that make the manner and proof of such notice of utmost importance. Indeed, proper service of the notice prescribed by statute is a prerequisite to a bank's accountability to an adverse claimant for funds in a deposit account…(Id). (Citing Ind. Code § 28-9-3-3.)

Vague returns of service or incomplete mail receipts may be inadequate service. Certified mail receipts which are not stamped by the post office and which contain no acknowledgment showing actual delivery are insufficient to demonstrate service (*Chester v. Green*, 120 F.3d 1091 (10th Cir.1997)). A mail receipt is insufficient if signed by mail room employee rather than intended recipient because it provides no evidence of actual, timely notice (*Gulley v. Mayo Foundation*, 886 F.2d 161 165–66 (8th Cir.1989)). See also *Scheerger v. Wiencek*, 34 F.Supp. 805 (W.D.N.Y.1940); *United States ex rel. Tar Products Co. v. Severin*, 6 F.Supp. 754, 755 (M.D.Pa.1934); *Murphy v. Campbell Soup Co.*, 44 F.2d 214, 216 (D.Mass.1930).

> "[S]ervice of notice" has a definite meaning, and unless otherwise provided by law means "personal service of the individual in such a way that the party who makes service may be in a position to make due proof thereof to the court." ... It is inherent in the concept of "service" that service of notice upon a person or entity imposes legal obligations and consequences that make the manner and proof of such notice of utmost importance.... [T]he term "serves" means legally sufficient service of notice upon which a due return of service can be made. *Hendricks County Bank & Trust Co. v. Guthrie Bldg....*, 663 N.E.2d 1180, 1185 (1996)

> "[a] signed return of service constitutes prima facie evidence of valid service 'which can be overcome only by strong and convincing evidence… **If the district court had no jurisdiction over the movant, its judgment is void**… it is questionable whether the presumption of service and the burden-shifting scheme referenced in (citations omitted) applies to returns of service that do not specify the address used or the identity of the individual who accepted the mailing…" (*Homer v. Jones-Bey*, 415 F.3d 748, 752-753 (7th Cir. 2005)). [Emphasis added].

Whether service is effective turns on the facts and circumstances of each case…" (*Ali v. Mid-Atlantic Settlement Services, Inc*., 233 F.R.D. 32, 37 (D.D.C. 2006)). The concepts used in the rules governing service of process are utilized for the purpose of providing a likelihood of bringing actual notice to the intended recipient," (*Minnesota Mining & Mfr'g Co. v. Kirkevold*, 87 F.R.D. 317, 324 (D.Minn.1980)).

The Pennsylvania Supreme Court held that service is effective if there is 'a sufficient connection between the person served and the defendant to demonstrate that service was reasonably calculated to give the defendant notice of the action against it.' (*Directv, Inc. v. Baratta*, No. Civ. A. 03–3265, 2004 WL 875541, at 2 (E.D.Pa. Mar.22, 2004) (quoting *Cintas Corp. v. Lee's Cleaning Services, Inc*., 549 Pa. 84, 700 A.2d 915, 920 (1997) cited in *Ali v. Mid-Atlantic Settlement Services, Inc*., 233 F.R.D. 32, 37 (2006)) Fn 3.)

"Service of process, under longstanding tradition in our system of justice, is fundamental to any procedural imposition on a named defendant." ". (*Anderson v. Gates*, 20 F.Supp.3d 114, 120 (2013), citing *Mann v. Castiel*, 681 F.3d 368, 372 (D.C. Cir.2012) (quoting Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc., 526 U.S. 344, 350, 119 S.Ct. 1322, 143 L.Ed.2d 448 (1999)). "A party must be properly served for the Court to obtain personal jurisdiction over that party. If the sufficiency of service is challenged, "the party on whose behalf service was made... has the burden to establish its validity." (*Hickory Travel Systems, Inc. v. TUI AG*, 213 F.R.D. 547, 551 (2003), citing *Wishart v. Agents for International Monetary Fund Internal Revenue Service*, 1995 WL 494586 at *2 (N.D.Cal.1995). "…service is not effective unless a plaintiff has substantially complied with its requirements." (Id).

> "[T]he party on whose behalf service is made has the burden of establishing its validity when challenged; to do so, he must demonstrate that the procedure employed satisfied the requirements of the relevant portions of [Federal] Rule [of Civil Procedure] and any other applicable provision of law" (*Anderson v. Gates*, 20 F.Supp.3d 114, 119 (2013)).

In *Anderson*, the plaintiff (Anderson) argued his method of service for all defendants was proper because his attempts were in good faith and defendant's employers would not provide him the defendants' personal or regular contact addresses. The court found the plaintiff did not satisfy the requirements of the rules, nor did Anderson demonstrate that he properly effected service on any of the defendants under D.C. law because he had not submitted any proof that defendants signed for or otherwise received the mailings or that any recipients of the mailings were authorized to accept service on behalf of defendants in their individual capacities. The court found that

> "…because defendants in their individual capacities have not been properly served, this Court lacks personal jurisdiction over them… (Id at 123). See also Hickory Travel Systems, Inc. v. TUI AG, 213 F.R.D. 547 (2003).

We find *Anderson* and *Hickory* analogous to the facts of this case and persuasive in their application

We find service of process herein was not effective because there was no connection between the person served and the defendant to demonstrate that service was reasonably calculated to give the defendant notice of the action against Respondent.

5. Pleadings or Papers are Considered Filed When They Are Received by FDA's Division of Dockets Management

Complainant took issue with our statement that "[t]o the extent that the Complainant has documentation responsive to this Order, it must file the documentation by pleading addressed and delivered physically to the Court, copy to the Respondent." Order at 2. Complainants argued our directive disregards 21 C.F.R. § 17.31(a)(4). It further argued:

> There is no requirement in Part 17 that a complainant physically deliver all pleadings to the ALJ, and creating additional procedural requirements beyond those already set forth in the Part 17 regulations is beyond the scope of the ALJ's authority and does not further the ends of justice.

And included a footnote:

> Moreover, given the volume of cases that CTP typically files before the ALJs (typically more than 100 complaints per week), it would be extraordinarily burdensome to require CTP to personally hand deliver the OALJ with paper copies of all filings, including complaints and proofs of service.

The Complainant confused requirements under 21 C.F.R. § 17.31 and the significance of the rule for purposes of filing with its obligations to the court. 21 C.F.R. §17.31 established the filing dates for pleadings or papers which carry great significance in terms of statutes of limitations and other obligations under the rules and law.

Complainant argued it typically filed before the ALJs (typically more than 100 complaints per week), it would be extraordinarily burdensome to require CTP to personally hand deliver the OALJ with paper copies of all filings, including complaints and proofs of service, thereby shifting to the OALJ the necessity of perusing FDMS to determine what, if any, pleadings have been filed.

The reverse of that statement is also true, that is the OALJ RECEIVES typically more than 100 complaints per week.

Complainant's position ignored the fact that it is extraordinarily burdensome, if not impossible, for OALJ to review filings or pleadings which OALJ is not aware of. We continue to advise the Complainant that response to a Court Order must be through pleading, not through "uploading" a document into a repository. To the extent that the Complainant has pleadings or documentation which it wants OCALJ to consider, it must file the documentation by pleading addressed and delivered physically to the Court, copy to the Respondent.

The action of Complainant in uploading a document to FDMS is not tantamount to filing a response with this Court and/or the undersigned ALJ. It is NOT notice to OCALJ. It is not incumbent on OALJ or the Presiding ALJ to thoroughly examine the entirety of FDMS, "regulations.gov", the Library of Congress or any other repository to determine if a party has complied with its Orders and/or determine what if any pleadings have been filed and when or where they were filed. The expectation is that any and all pleadings, with attachments, will be served on OALJ and/or the presiding ALJ in each and every case. Failure to do so may result in the imposition of sanctions 21 C.F.R. § 17.35.

OALJ has expectations of procuring a Case Management System at some time in the future. The advantage will be that all pleadings could be electronically filed, an efficient alternative for everyone concerned. In the meantime, OALJ is manually managing the docket.

Simply put, if OALJ is not provided copies of pleadings and documents, it will not be aware of them and cannot and will not rule on them.

WHEREFORE, Complaint (CTP's) response having been read and considered and the evidence in the administrative file having been read and considered, we make the following findings of fact and conclusions of law. We find:

1. Complainant failed to identify the Respondent in sufficient manner in the complaint to allow the court to determine which provision of 21 C.F.R. § 17.7 is applicable to the facts and allegations in this case.

2. Complainant failed to file a proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service as required by 21 C.F.R. § 17.7(b) with respect to Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) filed in FDMS.

3. Complainant failed to file an affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery; with respect to Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) filed in FDMS (21 C.F.R. § 17.7 (b)(1)).

4. Complainant failed to file a United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or; with respect to Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) filed in FDMS (21 C.F.R. § 17.7 (b)(2)).

5. Complainant failed to file a written acknowledgment of receipt by the Respondent or by the respondent's counsel or authorized representative or agent; with respect to Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) filed in FDMS (21 C.F.R. § 17.7 (b)(3)).

6. Complainant failed to file documentation demonstrating that the recipient identified as "Eldridge" in Document #0003 dated 10/08/2015 titled "Proof of Service for T and M United Corporation d/b/a BP Shop" (POS) filed in FDMS was authorized to accept service on behalf of Respondent.

7. Complainant failed to file a proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service as required by 21 C.F.R. § 17.7 with respect to Document #0004 titled "Signed POS for T and M United Corporation d/b/a BP Shop" (POD) filed in FDMS.

8. Complainant failed to file an affidavit or declaration under penalty of perjury of the individual serving the complaint by personal delivery; with respect to Document #0004 titled "Signed POS for T and M United Corporation d/b/a BP Shop" (POD) filed in FDMS (21 C.F.R. § 17.7 (b)(1)).

9. Complainant failed to file a United States Postal Service or similar mail delivery service return receipt record reflecting receipt; or; with respect to Document #0004 titled “Signed POS for T and M United Corporation d/b/a BP Shop” (POD) filed in FDMS. (21 C.F.R. § 17.7 (b)(2)).

10. Complainant failed to file an Written acknowledgment of receipt by the respondent or by the respondent's counsel or authorized representative or agent; with respect to Document #0004 titled “Signed POS for T and M United Corporation d/b/a BP Shop” (POD) filed in FDMS. (21 C.F.R. § 17.7 (b)(3)).

11. Complainant failed to file documentation demonstrating that the recipient identified as “Eldridge” in Document #0004 dated 10/08/2015 titled “Signed POS for T and M United Corporation d/b/a BP Shop” (POD) filed in FDMS was authorized to accept service on behalf of Respondent.

12. Complainant failed to serve Respondent, T and M United Corporation d/b/a BP Shop, with a copy of the complaint in this case as required by 21 C.F.R. § 17.7.

13. 21 C.F.R §17.11 does not require the presiding officer to *sua sponte* issue an initial decision within 30 days of the time the answer was due if the Respondent does not file an answer.

14. 21 C.F.R. § 17.11 does not excuse a party from complying with 21 C.F.R. § 17.32.

15. 21 C.F.R. § 17.32 requires that “…Any application to the presiding officer for an order or ruling **shall** be by motion. Motions **shall** state the relief sought, the authority relied upon, and the facts alleged… and **shall** be delivered to the presiding officer, and served on all other parties…” (Emphasis added)

16. If Complaint believes Respondent is in default it **shall** petition the court pursuant to 21 C.F.R. § 17.32 if it wants the presiding officer to consider the issue of default.

17. All parties seeking an order or ruling from the presiding office **shall** do so by filing a motion as set forth in 21 C.F.R. § 17.32.

18. Complainant failed to comply with our Order to Show Cause.

19. Complainant failed to Show Cause why the within complaint should not be dismissed.

20. Complainant failed to move for Default Judgment as required by the rules.

21. Complainant abandoned prosecution of this matter by its statement to the court that “CTP does not intend to file a motion seeking default in this matter” (21 C.F.R. § 17.35).

Whereupon, the above facts having been set forth, it be and is hereby ORDERED as follows:

1. The Administrative Complaint for Civil Money Penalties, FDA Docket No. FDA-2015-H-3507 filed on October 7, 2015 by the Center for Tobacco Products, Complainant, against T and M United Corporation d/b/a BP Shop,, be and is hereby DISMISSED *with prejudice* pursuant to 21 C.F.R. § 17.35.

Richard Goodwin -S

Digitally signed by Richard Goodwin -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001843973, cn=Richard Goodwin -S
Date: 2016.04.06 09:49:31 -04'00'

Richard C. Goodwin
U.S. Administrative Law Judge