DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION	DISTRICT ADDRESS AND PHONE NUMBER 850 Third Avenue Brooklyn, New York 11232 (718) 340-7000	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Mr. Joseph A. Errigo	PERIOD OF INSPECTION 3/26.....5/5/98	C. F. NUMBER 2431898
TITLE OF INDIVIDUAL President	TYPE ESTABLISHMENT INSPECTED Finished Pharmaceutical Manufacturer	
FIRM NAME Time Cap Labs, Inc.	NAME OF FIRM, BRANCH OR UNIT INSPECTED same	
STREET ADDRESS 7 Michael Avenue	STREET ADDRESS OF PREMISES INSPECTED same	
CITY AND STATE *(Zip Code)* Farmingdale, New York 11735	CITY AND STATE *(Zip Code)* same	

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Recently manufactured batches of the ANDA product Nitroglycerin 2.5 mg ER Capsules has included the use of [redacted] (anti-static powder) in the capsule pellet blends. This ingredient is not included in the ANDA approved formulation for this product. Batch examples include Nitroglycerin 2.5 mg ER Tablets, lots F056H and J062H.

Manufacturing records show that on 4/3/97 a [redacted] kg batch of Pellet "Anti-Static" Powder, consisting of [redacted] kg [redacted] and [redacted] kg [redacted] was produced and assigned lot # C009HI. There is no inventory record showing the usage of this material.

2. The firm has not established an acceptance range for the amount of timing solution used in the production of active stock pellets. For example, the Nitroglycerin stock pellet master record calls for the application of [redacted] gal of timing solution, whereas the quantity utilized in the two validation batches for the stock pellets were [redacted] and [redacted] gal., respectively. Review of recent stock pellet batches made during 1997, i.e., lots L053H, E074H and K037H show use of timing solution volumes between [redacted] to [redacted] gal.

3. The master batch records for manufacture of THE PELLETS FOR Nitroglycerin ER Capsules (2.5 mg, 6.5 mg, 9.0 mg) lacks adequate specificity in that:

a) There are no instructions for the seal coating of pellets prior to application of the active ingredient, in terms of how this application is to be performed, and the amounts of [redacted] and [redacted] to be used.

b) There are no specific instructions for the coating of the neutral pellets in terms of how the operation is performed or the quantities of [redacted] and [redacted] to be applied. Additionally, the quantities of those materials actually applied are not recorded.

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	Lawrence Farina Robert C. Horan	Lawrence Farina, Investigator Robert C. Horan, Investigator	5/5/98

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c) In the timing of active pellets, the manner in which the active ingredient is applied is not specified and the spray application of the ES # 1 (adhesive solution) does not identify spray rate, placement, and description of the spray apparatus, nor other significant operating parameters.

4. Two versions of the room temperature stability data summary sheets for 100 and 1000 capsule bottles of Comhist LA, lot L035E were observed at the firm. One version of the summary sheets found in a box of papers in the sample retention room included handwritten data for the 18 month test interval showing failure of the phenypephrine HCl to meet the first hour release rate for both bottle sizes. Versions of these same summary sheets maintained in the laboratory had typewitten entries for the 18 month test interval with passing results for the phenylephrine HCl first hour release rate.

5. Room temperature stability data summary sheets for Bisacodyl 5 mg E/C Pink Tablets, lot A014H, 100 count, 1000 count and blister pack indicate that the product failed the delayed release enteric coating test at the third month interval and that further stability testing of this lot was discontinued. The failing delayed release data could not be located in the laboratory notebooks.

However, stability data for this product at the 6 and 9 month test intervals was found in the laboratory work books but was not entered on the summary sheets. The summary sheets show evidence of the deletion of data at the 6 and 9 month test intervals.

There was no documented investigation or follow-up regarding the 3 month interval test failure.

6. As per the firm's stability program, accelerated stability studies are conducted on products for reasons including formulation revisions and changes in method of manufacture. However, there are no documented investigations and follow-up regarding any of the failing stability results from this testing.

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Examples include the following lots of Bisacodyl E/C Tablets which failed for potency and/or delayed release requirements:

Bisacodyl E/C Yellow Tablets	Bisacodyl E/C Pink Tablets	Bisacodyl E/C Brown Tablets
C014G	A014H	L043H
D012H	F013H	
E021H	F014H	
E023H	F015H	
K045H		

7. The firm has not conducted any annual product reviews since 1994.

8. Batch records for Phenylephrine HCl stock pellets, lot M087H showed reworks on two separate dates, each using [redacted] to remove ("wash" off) some of the previously applied timing material.

a) The batch records do not include any documentation of how this reworking was actually accomplished, what equipment was used, and the quantities and lot numbers of the washing material(s) employed. Additionally, the firm's rework SOP was not followed in that no rework procedure was prepared and submitted for review and approval by department supervisors.

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b) There is no validation data covering the performance of this "washing process".

c) This lot of reworked stock pellets was not put up on the firm's stability program, and the firm did not assess the stability of finished product batches Comhist LA Capsules, M069H and Com-time ER Capsules A025J, which were manufactured using these stock pellets.

9. The firm has no program for the periodic retesting of intermediate, active coated stock pellets (such as nitroglycerin stock pellets, chlorpheniramine maleate stock pellets, pheniramine maleate stock pellets etc.), and there is no established time limit for use of active pellets in finished drug products.

10. Batch manufacturing instructions for active coated stock pellets are for the most part poorly defined and/or non-specific. The following chart summarizes some examples:

Product	Operations not described/ or inadequately detailed
Phenylephrine HCl stock pellets, e.g. lots M087H and G051H	"Mix....in a suitable mixer...."; No speed specified; Description of spray gun and positioning of gun not provided; Procedure for manual application of active not described. For lot G051H [redacted] batch size), no information is given regarding the coating and timing of the pellets except for quantities of materials to be used.

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Pheniramine Maleate stock pellets, e.g. lots A021J and A022J	Batch record states to use a "suitable mixer"; Instructions state only to apply milled ingredients to neutral pellets but specific instructions to perform the coating are not given
Phenylpropanolamine HCl timed stock pellets, e.g. lots A029J and L075H	For coating of active, instructions do not describe how the operation is to be performed; Timing operation instructions list the quantities of materials to be used but not how the operation is to be performed; Batch instructions do not describe the splitting of the active coating operation into two parts nor how those parts are to be combined and blended following the timing operation
Chlorpheniramine Maleate timed stock pellets, e.g. lot K022G	No information is given regarding the coating with active ingredient, timing or coloring of the pellets except for quantities of materials to be used.
Phenyltoloxamine Citrate timed stock pellets, e.g. lot G050H	No description or parameters given for the spray gun to be used in applying [redacted] and no description of the manual application of active ingredient. Timing process not described; only quantities of materials to be used.

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11. Over the past 4 months, numerous batches of Aspirin E/C Tablets failed to meet the firm's in-process acid stage dissolution testing, and various portions of these batches had to be ~~[illegible]~~ further processed via the application of additional coating materials. None of these batches were covered by any documented investigation with regard to the "oos" lab results or the reasons for the batch ~~[illegible]~~ not meeting in-process specifications. (IF)

For example:

a) Aspirin 5 gr E/C Tablets (code 131R): of [redacted] batches tested/ [redacted] batches failed (lots K069H, L011H, L012H, L013H, L055H, L056H, A038J, A039J, B002J)

b) Aspirin 7 ½ gr E/C Tablets (code 35R): of [redacted] batches tested [redacted] batches failed (lots K024H,M032H, L0920H)

c) Aspirin 5gr E/C Tablets (code 9R): of [redacted] batches tested [redacted] batches failed (lots J090H, J005H)

d) Aspirin 81 mg E/C White Tablets (code 140R): of [redacted] batch tested [redacted] batch failed (lot B011J)

12. The batch records for Aspirin 7 ½ gr E/C Tablets lot M032H referenced in the above observation could not be located.

13. The batch records for Aspirin 325 mg (5 gr) E/C Tablets, lot B039G include a notation that approximately [redacted] tablets) of the batch which was reworked with additional coating materials was destroyed due to failure to pass the delayed release test, color pulling, and cracks in the tablet coating. There are no records of any documented investigation of this batch failure.

14. Batch records for Bisacodyl 5 mg E/C Pink Tablets, lots J022H and J060H, specify use of [redacted] for the enteric coating process, whereas an in-house produced [redacted] sealant was instead used. On finished product testing, both of these batches failed to meet the delayed release requirements. The lots were subsequently reworked using various coating materials including the originally called for [redacted]

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Also, although not documented in the batch records, management advised that the [redacted] coat of the tablets from both lots was first removed by washing with [redacted] prior to initiating the above reworking operations.

There were no documented investigations into the cause of these batch failures and no record of the review and approval of the reworking operations required by the firm's SOPs.

15. Review of the [redacted] mill usage log showed an entry for the milling of Papaverine HCl stock pellets lot C043J on 3/30/98. However, the batch record for this lot shows no milling of this product. According to management, for some products the firm recovers "grit" material left over from the active pellet timing operation. This material is [redacted] milled and then reapplied to the active pellets. None of these operations are documented in the batch production records.

16. Batch records for Cold Capsules, lot K028H include an investigation report regarding the finding of foreign green pellets in the product during the batch encapsulation run. The green pellets were noticed at the end of the filling of the blended seeds from one of the storage mules.

The investigation of this batch is deficient in that:
- it did not document any review of what products were blended and encapsulated on the same equipment immediately before and after lot K028H.
- the potential sources of the green pellets were not identified in the investigation
- analysis of the foreign material was limited to a check for presence of Phenylpropanolamine HCl.

Moreover, the 12/5/97 follow-up concluded that to prevent a reoccurrence of the incident, seals would be placed on the mule covers. No such seals were noted in use during this inspection.

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17. Cold Capsule blend, lot B090J was observed to be "on hold" in a mule on the mezzanine level floor. The batch record for this in-process batch revealed that there was no documentation in the batch record for:

a) transfer of blend to mules, blend weight or calculation of yield at this stage
b) in-process testing failures for assay of active pellets
c) to date there is no documented investigation of the blend testing failures

18. According to management, all batches of coated tablet products are visually inspected by QA after the final coating while in bulk carton storage. This inspection includes identification of visual defects and a comparison to a reference standard for size, color and appearance. No written SOP exits for this exam and no records are kept of these inspections and results.

For example, during inspection of the reject area, bulk cartons of Ferrous Sulfate E/C Red Tablets, lot L020H were observed bearing "Hold" stickers. On the face of the batch record for this lot was a separate handwritten note stating that the entire batch needed to be inspected "due to broken tablets". Reportedly, this problem was identified during the undocumented inspection of the lot.

The batch record included no entries regarding any problems with respect to tablet breakage, for example at the core production stage, or at the coated tablet imprinting stage.

19. The firm's SOPs do not address the need for conducting appropriate extended testing/ validation on batches subject to rework, formulation changes and /or significant manufacturing deviations. For example, on the following product batches, no such extended testing/ validation was performed:

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Product	Lot number	Operation
Cold Capsules	A009J	Batch reblended several times. Subsequently additional CPM added. Low assay result found for PPA at end of second reblend not investigated.
Cold Capsules	A052J	Reblended twice but operations not recorded in batch record. Additional CPM [redacted] more) and PPA [redacted] more), was added in the form of active pellets and third reblending performed. Lab notebook 9805/5 shows failing results for CPM in finished product capsules.
Phenylephrine HCl pellets	M087H	Pellets washed with [redacted] to affect increased active release. This resulted in first hour release of 41.12% and 3 ½ hour release of 69.11% (close to upper limit [redacted]).
Nitroglycerin 2.5 mg Tablets	F056H J062H	Use of anti-static powder on pellet blends
Bisacodyl 5mg E/C Pink Tablets	J022H J060H	1) Use of in-house [redacted] solution in place of [redacted] 2) Following finished product failure, removed [redacted] coat with [redacted] and recoated using [redacted] for the enteric coating.

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Bisacodyl 5mg E/C Yellow Tablets	All current lots	Increased the overage of active ingredient (from [redacted]% to [redacted]% as of 10/21/97) as per Master Formula revision. Incr[redacted]ed both the amount of enteric coating per coat and the number of coats of enteric coating to be applied as 9/28/95 as per Master Formula revision
Papaverine HCl 150 mg Capsules	C043J	Recovery of "grit" from active pellets and reapplication to batch

20. In 1990, large plastic HDPE bins called "Mules" were introduced into the production operations. These "Mules" are employed for the storage and gravity feed delivery of powder and pellet blends to the encapsulation and tableting equipment. They are also used for the storage, transfer and delivery of bulk tablets and capsules to the bottle filling lines. The following was noted with respect to these "Mules":

a) There are no records documenting the cleaning and usage of the "Mules".
b) Batch records provide no traceability of the specific "Mule(s)" used for the holding, transfer and delivery of in-process blends and finished products to the production and filling lines.
c) There is no process validation data covering the impact of the "Mules" on batch manufacturing operations FOR NITROGLYCERINE ER. CAPSULES. (F)

21. ~~The firm's~~ product coating processes lack established ~~validated~~ limits for operating parameters including the quantities of in-process coating materials to be applied. According to the firm's management, they primarily depend upon the "artistry' and skill of the coater. deleted (F)

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22. The firm has no change control SOP which describes the scope and procedure for the documentation, review and approval of changes in manufacturing processes and/or the records used for documenting those processes. Batch records show that changes have been made in the quantities of product ingredients and processes without documented change control review and approval (Examples are reflected in observations # 1,2,8,14,19 & 20).

23. Stocks of finished product labeling were observed stored in the general quarantine warehouse, rather than being held within a restricted access area.

24. Returned goods were not identified as such. For example, stocks of Ferrous Sulfate E/C Green Tablets lot 89K043H, returned by [redacted] was noted stored in the general quarantine warehouse area without identification as to its "returned goods" status.

25. The firm has no SOP for the qualification of vendors and contract laboratories, nor has such documented qualification been conducted The firm has been using the services of [redacted] for the testing of Purified Water, however, there has been no audit conducted at this contract laboratory.

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