DEPARTMENT OF HEALTH AND HUMAN SERVICESFOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

U.S. Food and Drug Administration, New Jersey District Office

10 Waterview Boulevard, 3rd Floor

Parsippany, NJ 07054

P: (973)-331-4900, F: (973)-331-4969

Industry Information: www.fda.gov/oc/industry

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

FEI NUMBER

DATE(S) OF INSPECTION

2/10, 2/11, 2/15, 2/18/2011

1/24, 1/25, 1/26, 1/28, 2/3, 2/4, 2/7, 2/9,

2243092

TO. Dr. David P. Jacobus, President

1.0:	
FIRM NAME	STREET ADDRESS .
Jacobus Pharmaceutical Co., Inc.	Industrial Research Building, Schalks Crossing Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536	Active Pharmaceutical Ingredient and Finished Dosage Form Mfr.

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

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

OBSERVATION 1

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

Specifically, your stability program for Dapsone 25 mg and 100 mg tablets does not include a stability-indicating method to monitor potential impurities.

OBSERVATION 2

Your stability testing program is not designed to monitor the stability characteristics of APIs.

Specifically, you do not evaluate the Dapsone drug substance for any impurities during stability testing of this API.

OBSERVATION 3

Your firm's quality unit is not involved in quality-related matters; the unit fails to review deviations from established specifications or procedures and does not adequately assess the need for corrective actions for deviations it is made aware of.

Specifically,

1. Excursions dated back to June 2009 for your controlled room temperature (CRT) stability chamber, in-process cold room, and transport and handling of in-process lots of your PASER granules product were not investigated. These include the following examples:

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

DATE ISSUED

allole James

Atul J. Agrawal, Consumer Safety Officer

2/18/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 1/24, 1/25, 1/26, 1/28, 2/3, 2/4, 2/7, 2/9, U.S. Food and Drug Administration, New Jersey District Office 2/10, 2/11, 2/15, 2/18/2011 10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 FEI NUMBER P: (973)-331-4900, F: (973)-331-4969 2243092 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dr. David P. Jacobus, President FIRM NAME STREET ADDRESS Jacobus Pharmaceutical Co., Inc. Industrial Research Building, Schalks Crossing Road CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Plainsboro, NJ 08536 Active Pharmaceutical Ingredient and Finished Dosage Form Mfr. a. For the CRT chamber used for long-term stability samples for APIs and finished drug products (e.g. Dapsone, # of Excursion Events Humidity Temperature Total Length of Time Dates 8/26-10/1/09 11 low & high N/A >14 days 5 >2 days 12/7/09-1/11/10 low low >19 hours 3/13-4/19/10 10 N/A high 8/19-9/28/10 4 low high >1 day. 12/28/10-1/26/11 4 low low >1 day For the in-process cold room used to store in-process PASER granule lots (storage requirement of # of Excursion Events Humidity Temperature Total Length of Time 3/18-4/9/10 N/A high >14 hours 7/8-8/9/10 16 N/A high >2 days You have no SOP that defines the monitoring and maintenance of your stability chambers and cold room. The stability chamber is not monitored on a frequent basis and has not been reviewed for adequacy since the sole qualification of the chamber in 1999. b. For the transport and handling of in-process PASER granule lots, I found the following high temperature excursions: # of Lots Dates # of Excursion Events Total Time Extreme Temp Recorded 6/12-7/22/09 7 >25 days (1 event=23 days) 82.9 °F 8 5 2/19-3/8/10 8 >20 hours 74.8 °F 6/4-7/21/10 1 day 73.7°F This product is transported to a contract coating facility and then to a contract packaging company. Your employees informed me that this product is to be maintained at between manufacturing steps and that data loggers are included during the transport and handling of in-process lots of PASER granules to ensure EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED REVERSE Atul J. Agrawal, Consumer Safety Officer 2/18/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 1/24, 1/25, 1/26, 1/28, 2/3, 2/4, 2/7, 2/9, U.S. Food and Drug Administration, New Jersey District Office 2/10, 2/11, 2/15, 2/18/2011 10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 FEI NUMBER P: (973)-331-4900, F: (973)-331-4969 2243092 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dr. David P. Jacobus, President FIRM NAME STREET ADDRESS Jacobus Pharmaceutical Co., Inc. Industrial Research Building, Schalks Crossing Road TYPE OF ESTABLISHMENT INSPECTED CITY, STATE AND ZIP CODE Active Pharmaceutical Ingredient and Finished Dosage Form Mfr. Plainsboro, NJ 08536 adequate storage and handling. No follow-up or investigations were conducted for the excursions listed above to determine root cause and potential impacts on the products and stability studies. Deviations during the production of 4-Aminosalicylic Acid (aka PAS) are not reviewed by your firm's quality unit at the time of occurrence. According to your firm's SOP # G-0023-01 titled "Deviations," your quality assurance department is responsible for reviewing and approving all proposed actions and corrective actions following deviations within of the event. Examples of deviations not reviewed by your QA unit within (b) (4) include: Lot Deviation Date of Deviation QA Review Date of Deviation 1163 pH drop during 2/15/09 3/19/09 3/10/09 4/8/09 1171 pH drop during (b) (4) malfunction* 1219 7/31/09 8/21/09 (b) (4) malfunction** 1364 10/20/10 12/13/10 (b) (4) malfunction also occurred during the 8 subsequent lots (1220-1227) of PAS manufactured after Lot 1219. Your QA unit did no assessment to determine appropriate corrective and preventative actions after the (b)(4) problems associated with lots 1219-1227. ** Production indicated that this may affect the (b) (4) and the production of the batch was continued. I observed that there is no written program that identifies and defines your quality unit's roles and responsibilities related to the manufacture, processing, packaging, holding, and distribution of drug products **OBSERVATION 4** Appropriate controls are not established over computerized systems. Specifically, computerized systems in your Quality Control laboratory do not have sufficient controls to prevent EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED REVERSE Atul J. Agrawal, Consumer Safety Officer 2/18/2011

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TO: Dr. David	i P. Jacobus, President		STREET ADDRESS		
Jacobus Pharm	aceutical Co., Inc.		200	ilding, Schalks Crossir	ng Road
CITY, STATE AND	ZIP CODE		TYPE OF ESTABLISHMENT	NSPECTED	
Plainsboro, NJ	08536		Active Pharmaceutical	Ingredient and Finishe	d Dosage Form Mfr.
systems conr Additionally	access to, changes to, or nected to your (b)(4) and one general account and these systems, and no com	(b) (4) instrun password for Q	nents with no audit trai C managers and analys	I to document such its is used for the op	an event. erating systems
OBSERVAT	ION 5		33		
sanitary cond Specifically, sampling are	ed in the manufacture, prolition. I observed powder-like rea for raw materials and cors and walls of this sample	esidues covering	approximately half of	the floors and walls	s of your firm's
OBSERVAT	TON 6				
	validation for a (b)(4) incre AS is inadequate.	ease in the batch	size ((b) (4)) of the active pharm	naceutical
b. There were c. The protoc times require d. There was	tion did not define or spece no pre-defined acceptant of and report noted changed. These specific change no provision for increase no provision for placing v	ce criteria to det ges in the steps (s were not outlir d sampling to de	ermine the reproducibile.g. size of the lead and justified in the emonstrate the robustness.	lity of the process. protocol or report.	ed and controlled. (b)(4)) and the
OBSERVAT	ION 7				100
3.5	ration of electronic equip	ment is not perf	ormed according to a w	ritten program desi	gned to assure
	EMPLOYEE(S) SIGNATURE		EMPLOYEE(S) NAME AND TITLE	(Print or Type)	DATE ISSUED
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CITY, STATE AND Z	aceutical Co., Inc.		TYPE OF ESTABLISHMENT	uilding, Schalks Crossii	ig Road
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Specifically, y (b)(4) us 2010. Based process of mo (b)(4) OBSERVATI Procedures de established and Specifically, y employees act The hose is strisk for bio-fil	Plainsboro, NJ 08536 Active Pharmaceutical Ingredient and Finished Dosage Form Mfr. Proper performance. Specifically, you failed to calibrate and ensure the proper performance of a critical parameter of the a critical parameter of the critical parameter of the critical parameter of the country of the c				
identified at a Specifically, I stored togethe	ding and storage contained all times to indicate the photoserved that drums of iter in your manufacturing entified as to its status. Yeacture.	in-process lots o areas and hallwa	ng of the batch. of PASER granules at the ays during manufacturing	ne same stage of ma	unufacture are without being
			70		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	AJA	EMPLOYEE(S) NAME AND TITLE Atul J. Agrawal, Consumer S.		2/18/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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OBSERVATION 10

Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints and investigations conducted for each drug product.

Specifically,

- a. Your quality unit failed to review all complaints and investigations related to finished drug products when conducting annual reviews. For example, the 2009 annual review for PASER Granules did not include a review of 3 complaints received and 9 manufacturing investigations conducted for the product. Three of these investigations were for the same issue (moisture content failures during manufacturing).
- b. You do not have an established procedure for evaluating finished drug products on at least an annual basis that would include a review of complaints and investigations. Your SOP titled "Product Quality Review" addresses annual reviews for APIs but not finished drug products.

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE

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DATE ISSUED

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Atul J. Agrawal, Consumer Safety Officer

2/18/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 1/24, 1/25, 1/26, 1/28, 2/3, 2/4, 2/7, 2/9, U.S. Food and Drug Administration, New Jersey District Office 2/10, 2/11, 2/15, 2/18/2011 10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 FEI NUMBER P: (973)-331-4900, F: (973)-331-4969 2243092 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dr. David P. Jacobus, President FIRM NAME STREET ADDRESS Jacobus Pharmaceutical Co., Inc. Industrial Research Building, Schalks Crossing Road CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Plainsboro, NJ 08536 Active Pharmaceutical Ingredient and Finished Dosage Form Mfr. THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE, IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE. DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED: ***AMENDED THE FDA 483 TO ORGANIZE THE OBJECTIONABLE CONDITIONS ACCORDING TO THE GMP SYSTEMS AND TO AMEND OBSERVATION 4 FOR A TYPOGRAPHICAL ERROR.*** LABORATORY CONTROL SYSTEM OBSERVATION 1 The written stability program for drug products does not include reliable, meaningful, and specific test methods. Specifically, your stability program for Dapsone 25 mg and 100 mg tablets does not include a stability-indicating method to monitor potential impurities. **OBSERVATION 2** Your stability testing program is not designed to monitor the stability characteristics of APIs. Specifically, you do not evaluate the Dapsone drug substance for any impurities during stability testing of this API. EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED EMPLOYEE(S) SIGNATURE REVERSE Atul J. Agrawal, Consumer Safety Officer 2/24/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

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CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536	Active Pharmaceutical Ingredient and Finished Dosage Form Mfr.

QUALITY SYSTEM

OBSERVATION 3

Your firm's quality unit is not involved in quality-related matters; the unit fails to review deviations from established specifications or procedures and does not adequately assess the need for corrective actions for deviations it is made aware of.

Specifically,

- 1. Excursions dated back to June 2009 for your controlled room temperature (CRT) stability chamber, in-process cold room, and transport and handling of in-process lots of your PASER granules product were not investigated. These include the following examples:
- a. For the CRT chamber used for long-term stability samples for APIs and finished drug products (e.g. Dapsone, (b) (4) yridine):

Sec. 1	1625 22-507 58 00.055	877.00 A/4.0		
Dates	# of Excursion Events	Humidity	Temperature	Total Length of Time
8/26-10/1/09	11	low & high	N/A	>14 days
12/7/09-1/11/10	5	low	low	>2 days
3/13-4/19/10	10	high	N/A	>19 hours
8/19-9/28/10	4	low	high	>1 day
12/28/10-1/26/11	4	low	low	>1 day

For the in-process cold room used to store in-process PASER granule lots (storage requirement of

of Excursion Events Humidity Temperature Total Length of Time Dates high >14 hours 3/18-4/9/10 N/A 16 N/A high 7/8-8/9/10 >2 days

You have no SOP that defines the monitoring and maintenance of your stability chambers and cold room. The stability chamber is not monitored on a frequent basis and has not been reviewed for adequacy since the sole

	EMPLOYEE(S) SIGNATURE		EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
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FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page 2 of 6

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 1/24, 1/25, 1/26, 1/28, 2/3, 2/4, 2/7, 2/9, U.S. Food and Drug Administration, New Jersey District Office 2/10, 2/11, 2/15, 2/18/2011 10 Waterview Boulevard, 3rd Floor Parsippany, NJ 07054 FEI NUMBER P: (973)-331-4900, F: (973)-331-4969 2243092 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dr. David P. Jacobus, President FIRM NAME STREET ADDRESS Jacobus Pharmaceutical Co., Inc. Industrial Research Building, Schalks Crossing Road TYPE OF ESTABLISHMENT INSPECTED CITY, STATE AND ZIP CODE Plainsboro, NJ 08536 Active Pharmaceutical Ingredient and Finished Dosage Form Mfr. qualification of the chamber in 1999. b. For the transport and handling of in-process PASER granule lots, I found the following high temperature excursions: # of Lots # of Excursion Events Total Time Dates Extreme Temp Recorded 6/12-7/22/09 8 >25 days (1 event=23 days) 82.9 °F 5 8 >20 hours 74.8 °F 2/19-3/8/10 73.7 °F 6/4-7/21/10 1 day This product is transported to a contract coating facility and then to a contract packaging company. Your (b) (4) between manufacturing steps and employees informed me that this product is to be maintained at that data loggers are included during the transport and handling of in-process lots of PASER granules to ensure adequate storage and handling. No follow-up or investigations were conducted for the excursions listed above to determine root cause and potential impacts on the products and stability studies. 2. Deviations during the production of 4-Aminosalicylic Acid (aka PAS) are not reviewed by your firm's quality unit at the time of occurrence. According to your firm's SOP # G-0023-01 titled "Deviations," your quality assurance department is responsible for reviewing and approving all proposed actions and corrective actions following deviations within (b)(4) of the event. Examples of deviations not reviewed by your OA unit within (b) (4) include: Lot Deviation Date of Deviation QA Review Date of Deviation 2/15/09 1163 pH drop during 3/19/09 3/10/09 4/8/09 1171 pH drop during (b) (4) malfunction* 7/31/09 1219 8/21/09 (b) (4) malfunction** 1364 10/20/10 12/13/10 (b) (4) malfunction also occurred during the 8 subsequent lots (1220-1227) of PAS manufactured after This EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED REVERSE Atul J. Agrawal, Consumer Safety Officer 2/24/2011

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FIRM NAME	. 10		STREET ADDRESS		
Jacobus Pharm CITY, STATE AND	naceutical Co., Inc.		Industrial Research Bu		ng Road
Plainsboro, NJ	Car Darwing		Active Pharmaceutical		d Dosage Form Mfr
	our QA unit did no asse				
** Production of production of I observed the related to the OBSERVAT	problems associated with on indicated that this ma of the batch was continu- nat there is no written pre- e manufacture, processing	th lots 1219-1227. The lots 1	(b)(4) ize. The fies and defines your quiding, and distribution of done at least annually a	ality unit's roles an	and the
conducting a 3-complaints were for the b. You do no would include	lity unit failed to review nnual reviews. For exa received and 9 manufa same issue (moisture copt have an established ple a review of complaints we for APIs but not finished	imple, the 2009 and cturing investigation tent failures duri procedure for evalu- ts and investigation	nual review for PASER ions conducted for the ping manufacturing). nating finished drug proms. Your SOP titled "P	Granules did not in product. Three of the ducts on at least an	nclude a review of nese investigations annual basis that
FACILITIES	S AND EQUIPMENT S	YSTEM			
OBSERVAT	TON 5				
Appropriate	controls are not establis	hed over compute	rized systems.	9	
unauthorized	computerized systems is access to, changes to, changes to, ected to your (b) (4) an	or omission of data	a. Electronic data can b nents with no audit trail	to document such	nputerized
SEE	EMPLOYEE(S) SIGNATURE	1 .	EMPLOYEE(S) NAME AND TITLE	(Print or Type)	DATE ISSUED
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FIRM NAME	41.5400000,1100,4001		STREET ADDRESS		
Jacobus Pharm	naceutical Co., Inc.		Industrial Research B	uilding, Schalks Crossi	ng Road
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OBSERVAT	TION 6	33 AVENUE 33 AVENUE			- 100 140
sanitary cond Specifically, sampling are	dition. I observed powder-lik	ke residues covering d components. I al	ding of drug products a g approximately half of so observed leaking wa	the floors and wall	s of your firm's
OBSERVAT	TION 7		8		
Routine calib proper perfor		quipment is not per	formed according to a v	written program des	igned to assure
(b) (4) u (b) (4), 2010. Based process of m	sed during the product a critical parameter of l on your firm's record	tion of the finished f the (b)(4) s, the (b)(7) of PASER granules	per performance of a drug product PASER g The body was a since June 30, 2010. In the body with no tag or still body and the since June 30 and the body with no tag or still body and the b	ranules to monitor to s due for calibration b)(4) basis in the man n addition, I observe	the (b)(4) n on June 30, nufacturing ed another
PRODUCTIO	ON SYSTEM			Maria Managaran Sana	
OBSERVAT	ION 8		-		
	validation for a (b)(4) in	ncrease in the batch	size (b) (4)) of the active pharm	maceutical
	EMPLOYEE(S) SIGNATURE	Δ	EMPLOYEE(S) NAME AND TITLE	(Print or Type)	DATE ISSUED
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6.	EALTH AND HUMAN SERVICES DRUG ADMINISTRATION	s	
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times required. These specific changes were not outli d. There was no provision for increased sampling to d e. There was no provision for placing validation batch OBSERVATION 9	lemonstrate the robustne		
employees acquiring for use at valve to the hose is stored (hung) in several loops and routine risk for bio-film buildup. Sampling is conducted by detailed to the hose is stored (hung) in several loops and routine risk for bio-film buildup.	is inconsistent with a by using a plastic hose ly connected to the port	actual practice. I ob that is approximate in between uses, the	bserved ely feet long. ous increasing the
OBSERVATION 10	ar and a second		
All compounding and storage containers used during to identified at all times to indicate the phase of processions of Specifically, I observed that drums of in-process lots of stored together in your manufacturing areas and hallwadequately identified as to its status. You have no confurther manufacture.	ng of the batch. of PASER granules at the rays during manufacturing trols in place to prevent	ne same stage of maing and QC testing vote mix-ups of in-process.	nufacture are without being cess material for
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE	(Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE	Atul J. Agrawal, Consumer Sa	afety Officer	2/24/2011