DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

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 OBSERVED:

Quality System

OBSERVATION 1

Investigations of an unexplained discrepancy did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

a.) Deviation Report # 007 for Chlordiazepoxide Hydrochloride and Clidinium Bromide USP, capsules 5mg and 2.5mg, batch E00810, found one capsule with a weight of 38.7mg during content uniformity testing, indicating an empty capsule. A weight of approximately [redacted] mg was expected. The batch was passed through the capsule polisher fitted with an empty capsule separator as well as through the capsule weigh checker during the manufacturing process. The investigation did not extend to review other batches of Chlordiazepoxide Hydrochloride and Clidinium Bromide USP, capsules 5mg and 2.5mg or other encapsulated products produced using the same encapsulator, capsule polisher and empty capsule separator. No definitive root cause was determined.

b.) Deviation Report # 004 for Lorazepam Tablets USP, 0.5mg, batch A02510, found the wrong product description was included in the certificate of analysis. The investigation states the error occurred because the laboratory personnel used outdated information to prepare the certificate of analysis. The investigation failed to review those certificates of analysis issued prior to the deviation.

c.) Deviation Report # 005 for the blend of Hydrochlorothiazide Tablets USP, 25mg, batch D00910, found black particles in the blend during analysis. The investigation found the [redacted] blade rotor was off center, allowing the blend to enter the gap between the chamber wall and the shaft. The investigation did not review prior batches processed on the [redacted] for similar problems.

d.) Deviation Report # 011 for Purified Water USP, batch # 10MY011, found the total heterotrophic plate count to be 101 cfu/mL. The specification is [redacted] cfu/mL. Though this lot of Purified Water was rejected and not used in the production of any products. No review of other lots of purified water was performed as part of the investigation. No microbial testing is conducted on finished products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

OBSERVATION 2

Written procedures are not established for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.

Specifically, the SOP # QA-041, Revision # B, "Annual Product Review", limits the annual review to the last (b)(4) batches of products produced within a given calendar year. There is no assurance that a representative review is completed. For example;

a.) (b)(4) batches of Colchicine Tablets, USP 0.6mg were produced in 2009. The 2009 annual product review includes review of (b)(4) batches of finished product produced from 05/09/09 through 08/12/09. (b)(4) batches produced between January 2009 through May 2009 are not included in the review.

b.) (b)(4) batches of Chlordiazepoxide HCl and Clidinium Br Capsules, USP 5mg / 2.5mg were produced in 2009. The 2009 annual product review includes review of (b)(4) batches of finished product produced from 08/28/09 through 12/29/09. (b)(4) batches produced between anuary 2009 through August 2009 are not included in the review.

c.) (b)(4) batches of Epidrin (Isometheptene Mucate, Dichloralphenazone, and Acetaminophen 65mg/100mg/325mg) Capsules were produced in 2009. The 2009 annual product review includes review of (b)(4) batches of finished product produced from 04/2/09 through 12/18/09. (b)(4) batches produced between January 2009 through April 2009 are not included in the review.

OBSERVATION 3

Employees are not given training in current good manufacturing practices.

Specifically, a review of SOP# TRN-001, Revision A, "Training of Production Employees" and the training documentation found that no initial or continuing CGMP training is conducted with personnel involved with manufacturing, packaging, or testing of drugs products produced at your facility.

OBSERVATION 4

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, there is no annual visual inspection of reserve samples.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator MK	01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

Facilities and Equipment System

OBSERVATION 5

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a.) There is no assurance that the reproducibility of the cleaning procedure has been demonstrated to prevent cross contamination in that one cleaning verification was performed for Felodipine 10mg tablets on multiuse equipment on 3/28/08. Felodipine was manufactured three times in 2010 for Felodipine Tablets 2.5 mg batch B01210, and Felodipine Tablets 10 mg batches E03710, and F02810 on the (b) (4) mixer and cleaned. No cleaning verification was performed to assure the cleaning procedure was effective to prevent cross contamination to commercial products manufactured on the same equipment.

b.) On 12/13/10, during the packaging of Epidrin (Isometheptene Mucate, Dichlorophenazone and Acetaminophen 65mg/100mg/325mg) Capsules, batch # L00210 in packaging room #(b) and Folic Acid USP, 1mg, batch # L01710 in packaging room #(b) particulates from the (b) (4) torque wheels or the bottle caps were observed discharging from the cap and torque wheel interface potentially entering the finished product bottle prior to capping.

OBSERVATION 6

Equipment for adequate control over air pressure, humidity, and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, there is no assurance that products are held or manufactured under the appropriate environmental conditions. For example;

a.) There is no temperature mapping of the warehouse used for the storage of raw materials, in-process material, and finished products.

b.) There is no air pressure monitoring in the manufacturing rooms to assure negative pressure is maintained in the manufacturing rooms to prevent cross contamination between products.

c.) There is no monitoring of temperature and humidity in the manufacturing rooms and packaging rooms.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

OBSERVATION 7

Written procedures for cleaning and maintenance fail to include instructions for protection of clean equipment from contamination prior to use.

Specifically,

a.) There is no designated area for the storage of clean equipment to prevent contamination or ensure clean status. The (b) (4) tablet press, equipment # 28, and (b) (4) mixer, equipment # 19, were found stored in the warehouse near the loading dock and labeled as cleaned. The equipment was placed approximately 5 feet away from the door where dampness from water run off from the exterior of the building had entered from under the exterior door

b.) Brushes in manufacturing room # (b) (4) used for the cleaning of equipment were found stored between piping and soiled scouring pads in manufacturing rooms # (b) (4) and # (b) (4) used for the cleaning of equipment were found stored between the wall mount bracketing for the water pipe

c.) Capsule rings used for the filling of encapsulated products were found uncovered and openly stored on a plastic pallet and cart in manufacturing room # (b) (4) The room was released for use, but not in use at the time.

d.) A water hose used for cleaning manufacturing equipment, containing stagnant water, was found stored in a closed container for later use in cleaning of manufacturing equipment.

OBSERVATION 8

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically,

a.) Paint chips on the floor of manufacturing room # (b) (4) and what appeared to be flaking paint on the frames of the HEPA filters on the ceiling above the (b) (4) mixer. This room and mixer were used for the recent production of Folic Acid Tablets, 1mg batches L02110 and L02310, and Lorazepam Tablets USP, 0.5 mg batches L02510 and M00110.

b.) The frames of the HEPA filters on the ceiling above the (b) (4) blender in manufacturing room # (b) (4) appeared to have flaking paint used. This room and mixer were for the recent production of Furosemide Tablets USP, 40mg batches L01810, L01910, and L03110.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
TO: Mr. Hasmukh Doshi, President	
FIRM NAME Excellium Pharmaceuticals, Inc	STREET ADDRESS 3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY Fairfield, NJ 07004-2903	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

OBSERVATION 9

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

a.) The qualification of the (b) (4) purified water purification system is inadequate in that SOPs for the use, maintenance, sanitization of the system, and calibration of in-line sensors are not approved. The performance qualification was conducted over 14 weeks from July 2010 through September 2010. The qualification does not cover the seasonal variations in the water supply. There are no as built drawings of the system. Water from the systems was used in the manufacture of Furosemide Tablets USP, 40 mg batch # J01110, Epidrin Capsules batch # J01210 and batch # L01010.

b.) The use of a (b) (4) tablet press, equipment #28, and (b) (4) mixer, equipment # 19, as portable equipment installed without installation procedures to include requirements such as checking the equipment level prior to use.

c.) The use of unqualified balances and scales in the quality control laboratory, manufacturing and packaging areas. These balances and scales are used for the analytical weighing of standards, samples, raw materials used in manufacture, and in-process verifications.

d.) The use of scales and balances used for weighing stored on carts in the manufacturing and packaging rooms that do not allow for a stable foundation for the in-process weight verifications of tablets and capsules.

e.) 5 of 5 (b) (4) balances inspected in the manufacturing and packaging operations are missing the bubble level indicators. The balances are used for the in-process verification of tablet or capsule weights.

f.) The use of fabric mats in manufacturing and packaging rooms for operators to wipe their feet prior to entering and exiting to prevent cross contamination between products. There is no assurance the mats can be adequately cleaned.

g.) The use of wood pallets in manufacturing rooms (b) (4) and (b) (4) and packaging rooms (b) and (b). There is no assurance the wood pallets can be adequately cleaned..

h.) The use of fibrous drop ceilings in the manufacturing hallways and packaging rooms (b) (4) There is no assurance the fibrous drop ceilings cannot adequately cleaned.

i.) The use of portable floor fans in the packaging rooms (b) (4) The use of the fans can potentially introduce debris into the packaging operations.

j.) Tape residue was found on rack 'U' of the drying racks used for drying of in-process blend material. There is no assurance that tape residue can be adequately cleaned.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michael R. Klapal, Investigator	DATE ISSUED 01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

Production System

OBSERVATION 10

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there is no process validation to support changes made to the following drugs;

a.) The process validation of Phenobarbital Tablets USP, 100mg conducted in May 2002 supports the production of a (b) (4) tablet batch size. The master batch record was changed in July 2002 to increase the batch size to (b) (4) tablets. There is no process validation supporting this change or a documented impact assessment of the validation status. Examples of batches produced with the (b) (4) tablet batch records include batch numbers B01710, E00410, and K04510.

b.) The process validation of Epidrin (Isometheptene Mucate, Dichloralphenazone, and Acetaminophen 65mg/100mg/325mg) Capsules conducted in April 2000 supports the production using (b) (4) and (b) (4) kg of (b) (4), with a target capsule weight of (b) (4) mg. During the process validation, the master batch record was updated to revision 1 to increase the quantity of (b) (4) to (b) (4) kg and increased the target capsule weight to (b) (4) mg. One batch was produced with the initial version of the master batch record and two with revision 1. The master batch record was changed in September 2000, revision 2, to remove the use of (b) (4) as part of the granulation process. There is no process validation supporting these changes. Examples of batches produced with the updated formulation include D01010, K04210, and L00210.

Packaging and Labeling System

OBSERVATION 11

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the expiration dates assigned to batches of finished drug products are determined based on the quality control release date as per SOP QA-003, Revision# D, "Raw Material and Finished Product Release Stickers". The following examples have expiry dates that exceed the target 30 months expiry date from the date of manufacture (DOM).

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

Product	Batch #	DOM	Expiry as labeled	DOM plus 30 months
Epidrin (Isometheptene Mucate, Dichloro-phenazone and Acetaminophen (65/ 100/ 325mg)) Capsules	D01010	4/13/10	11/2012	10/2012
Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules, USP 5.0mg and 2.5mg	K02710	10/19/10	6/2013	4/2013
Phenobarbital Tablets USP, 100mg	B01710	2/22/10	9/2012	8/2012
Hydrochlorothiazide Tablets USP, 25mg	E03410	6/24/10	1/2013	12/2012

OBSERVATION 12

Labeling and packaging materials are not representatively sampled upon receipt and before use in packaging and labeling of a drug product.

Specifically, SOP# 045, Revision C, "Packaging Components Release/Rejection" states that (b) pieces of labels and inserts will be collected and checked against their master proof. Examples include;

a.) (b) (4) bottle labels on (b) rolls were received for Phenobarbital USP, 100mg Tablets, USP labels, Lot# 9LC014. 25 labels from 5 rolls were verified against the master proof.

b.) (b) (4) bottle labels on (b) rolls were received for Epidrin, Lot# 10LC018. 20 labels from 5 rolls were verified against the master proof.

c.) (b) (4) bottle labels on (b) rolls were received for Hydrochlorothiazide Tablets USP, 25mg, Lot# 10LC016. 20 labels from 5 rolls were verified against the master proof.

Laboratory Systems

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

OBSERVATION 13

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a.) Thin layer chromatography (TLC) is used for the quantitative determination of related compounds for stability by visual means of comparing standard and sample spots. Examples include Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules, USP 5.0mg and 2.5mg batch numbers K0148, H0159 and E00610 with related compounds limits of [redacted (b) (4)] There are no quantitative results. The results are reported as None Detected or Meets Requirement.

b.) The system suitability specifications for the relative standard deviation (%RSD) for replicate injections exceed the current USP specifications. Examples include;

1) Method # M-QC-073, Revision#: New, "Testing Procedures for Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules, USP 5.0mg and 2.5mg", indicates the %RSD for 5 replicate injections is [redacted (b) (4)]% where USP indicates NMT 2.0% for replicate injections. This method was used for the testing of batch numbers K0148, H0159, and E00610.

2) Method # M-QC-046, Revision#: 6, "Testing Procedure for Phenobarbital Tablets, USP 15mg, 30mg, 60mg and 100mg", indicates the %RSD for 5 replicate injections is [redacted (b) (4)]% where USP indicates NMT 2.0% for replicate injections. This method was used for the testing of batch numbers, B01710, E00410, and K04510.

OBSERVATION 14

Accelerated stability studies, combined with basic stability information, used to support tentative expiration dates are not supported with ongoing full shelf life studies.

Specifically, during the drying cycles for in process blends, the drying oven malfunctioned on three separate occasions before the end of the drying cycles; on 6/16/10 for the blend of Furosemide Tablets USP, 80mg, batch F01610; on 8/06/10 for the blend of Furosemide Tablets USP, 40mg, batch H00810; and on 8/18/10 for the blend of Epidrin, batches H01710 and H01810. The finished product for Furosemide Tablets USP, 40mg, batch H00810 and Epidrin batch H01710 were placed on 3 month accelerated stability. The finished product for Furosemide Tablets USP, 80mg, batch F01610 was not placed on 3 month accelerated stability and no stability samples were placed on controlled room temperature for the shelf life of the product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	12/13/2010 - 01/06/2011* FEI NUMBER 3001611969

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Hasmukh Doshi, President

FIRM NAME	STREET ADDRESS
Excellium Pharmaceuticals, Inc	3 Oak Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fairfield, NJ 07004-2903	Pharmaceutical Manufacturer

OBSERVATION 15

The use of instruments not meeting established specifications was observed.

Specifically, though the calibration documentation indicates HPLC # (b) (4) passes specification of (b) (4) for the correlation coefficient (R^2), review of the supporting raw data found discrepancies in the peak areas obtained at (b) (4) (b) (4) The results for the (b) (4) concentrations appear to be nearly identical in response even though there is a 12.5 % difference in their respective concentrations. HPLC # (b) (4) was used for the analysis of Furosemide Tablets USP, 40mg (blend) batch # L01410, Furosemide Tablets USP, 80mg batch # L00610, and Folic Acid Tablets, 1mg batch # L01710.

OBSERVATION 16

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically, Laboratory records do not always include references to the methods, equipment, instruments, or reagents used during the analysis. Examples include;

a.) Phenobarbital Tablets USP, 100mg, batch # E00410
b.) Furosemide Tablets USP, 40mg, batch # B01910
c.) Furosemide Tablets USP, 80mg, batch # F01610

*** DATES OF INSPECTION:**
12/13/2010(Mon), 12/14/2010(Tue), 12/15/2010(Wed), 12/16/2010(Thu), 12/17/2010(Fri), 12/20/2010(Mon), 12/21/2010(Tue), 12/28/2010(Tue), 12/29/2010(Wed), 01/04/2011(Tue), 01/06/2011(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Michael R. Klapal, Investigator	01/06/2011