DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER (NOL-DO - temporary office)	DATE(S) OF INSPECTION
297 Plus Park Blvd. Nashville, TN 37217 615-695-4654	1/25/06, 1/26/06, 1/27/06
	FEI NUMBER 3004153061

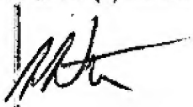
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Reginald C. Funches, quality manager

FIRM NAME	STREET ADDRESS
PharMEDium Services, LLC dba COMPASS	913 N. Davis Avenue
CITY, STATE AND ZIP CODE Cleveland, MS 38732	TYPE OF ESTABLISHMENT INSPECTED drug manufacturer

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

1) Failure to perform finished product testing for identity, potency, and sterility as a requirement for release of every lot produced.
2) The quality control unit is not designated in writing and given the responsibility and authority to accept and reject incoming raw materials, in process tests, and finished product release, among other functions. Further, certain production technicians, who are not employees of the quality department, are given authority to approve/release labeling for use during the packaging and labeling of finished products.
3) Finished product quarantine and release procedures are inadequate in that (b)(4) units of lot #060120087, 0.2 mg/mL Hydromorphone HCl in 0.9% Sodium Chloride, 30 ml fill in a (b) (4), are documented as "shiped" when the lot was Quarantined per form #F-611-2 on 1/13/06.
4) In process product is not adequately labeled to identify the contents of the product. Specifically, (b) (4) (b) (4) in (b) (4) (b) (4), and only (b) (4) has a (b) (4), (b) (4) (b) (4), therefore, it is possible for this label to be lost or removed before labeling of the finished product.
5) (b) (4) are in at least (b)(4) of the (b)(4) laminar air flow hoods in the production clean room. One technician (b) (4). This practice could lead to a mix up.
6) There is no ongoing stability program in that one lot per year of each product is not placed on stability to validate the product maintains potency and sterility through its labeled expiration date.
7) Failure to maintain reserve samples of products manufactured.
8) Line clearance activities are inadequate in the labeling and pouching area in that (b) (4) of multiple drug products are (b) (4).
9) Failure to initiate investigations into production deviations immediately upon the event occurring if the event occurs when quality assurance staff are not present (ie: (b) (4)). Specifically, two in-process (b) (4) Morphine Sulfate (b) (4) lot (b) (4) Hydromorphone (b) (4) syringe lot (b) (4)) were observed in a quarantine area, but review of the accompanying batch production records did not reveal the reason for their quarantine status.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		Steven D. Dittert, investigator	1/27/06

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to the health. A copy of such report shall be sent promptly to the Secretary."