

Form TI-1 Case Resolution

Case Status	<input type="checkbox"/> Open	<input checked="" type="checkbox"/> Closed
RCODE: <u>65733</u>		
Region: <u>1</u>		
OLD - Complete Name, Address, Contact, Phone Number: Universal Machine 525 West Vine Street Pottstown, Pennsylvania 19464		
NEW - Complete Name, Address, Contact, Phone Number: Aventis Pharma Manati, Puerto Rico Contact: Domingo Lopez 787-884-7911 Domingo.Lopez@Aventis.com Alternate Contact: Terry Mead, Head of EHS for North America Drug Product and Commercial Operations, Aventis (TerryMead@aventis.com ; 816-966-3402)		
Agreement State Licensee? (Double Check)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Moved to an Agreement State?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Describe Follow-up: (Telephone, Internet, Chamber of Commerce, Other) Don Scheirer, Engineer, Universal Machine (610-323-1810). Terry Mead, Head of EHS for North America Drug Product and Commercial Operations, Aventis (TerryMead@aventis.com ; 816-966-3402). Universal Machine is a manufacturer of industrial equipment including bottling equipment. The devices in question were obtained on behalf of Aventis for use on a machine that was being installed in its Manati, Puerto Rico facility (called Aventis Pharma) to bottle Nasacort AQ. For some reason, the first device shipped was not acceptable and was returned (as confirmed by the vendor). The second device is in use. Aventis has apparently added a second gauge at some point.		
Describe Communication with Registration Vendor: Vendor confirmed that it shipped one device to Universal, then shipped a second to replace the first. It confirmed that the first was returned		
Vendor Follow-up Action:		
Final Action Taken:		
Cause of Bad Address/Lesson Learned:		

Form TI-2: Device Information

RCODE: <u>65733</u>								
ID	Model Number	Serial Number	Isotope	Activity (mCi)	Sold Date	Vendor	Status (A or N)	Comments
1	FT-50	5661	²⁴¹ Am	100	19942	1586-70GL	A	
2	FT-50	113231	²⁴¹ Am	100	19943	1586-70GL	A	
For additional GLD's received by the licensee identified during the inspection:								
ID	Model Number	Serial Number	Isotope	Activity	Sold Date	Vendor	How obtained	Comments
1	FT-50	116393	²⁴¹ Am	100	?	1586-70GL	Purchase	

Status Codes:

A - Source accounted for

N - Source not accounted for

Form TI-3: General Licensee Inspection Documentation

RCODE: <u>65733</u>	
General Licensee Information:	
<input type="checkbox"/>	Check Box if Current Complete Name, Mailing Address, Contact, and Phone Number is Same as Provided by ORNL. If not, include correct information below:
<input type="checkbox"/>	
Results of inspection: (check the appropriate boxes)	
X	The general licensee of record is located at the address of record and
X	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for
<input type="checkbox"/>	The general licensee of record is <u>not</u> located at the address of record, however GLD are being used under new ownership at the address of record and
<input type="checkbox"/>	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for
<input type="checkbox"/>	The general licensee of record is <u>not</u> located at the address of record, however they are using GLD at another location and
<input type="checkbox"/>	all GLD are accounted for
<input type="checkbox"/>	<u>not</u> all GLD are accounted for;
<input type="checkbox"/>	Neither the general licensee of record nor the facility operated by the general licensee are located at the address of record and the site has been abandoned or is being used for an alternate purpose.
<input type="checkbox"/>	Other: (explain)
Gauge Information:	
ID	For each gauge for which status is unaccounted for (see last column of Form TI-2), provide any conclusions about location of the gauge:
<input type="checkbox"/>	
<input type="checkbox"/>	

The gauge and another such gauge are in use at an Avantis facility in Puerto Rico.

Inspector: Keith Brown, Health Physicist
Nuclear Materials Safety Branch 2

Approved By: John D. Kinneman, Chief
Nuclear Materials Safety Branch 2