FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Esub Case ID(s) Printed:

12507321	12647166	12663744	12703541	12703552	12703553	12723312
12744948	12744949	12791635	12802572			

Run by: **STEPPERH**

Date - Time: **28-OCT-2016 08:20 AM**

Total number of cases (Esub): 11

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12507321

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 18-Jun-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 26-Sep-2016 **Mfr Rcvd Date:** 15-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000024 **Application #:** 207318

Patient Information:

Age: 73 YR **Sex:** Female **Weight:** 54.88 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		17 MG/	Oral	17 mg, qd	Parkinson's disease psychosis	15-Jun-2016	17-Jun-2016
2	Nuplazid					Delusion		
3	Nuplazid					Dementia		
4	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	4 Day	NA	NA	3139179			ACADIA PHARMACEUTICALS
2	Nuplazid	4 Day	NA	NA				ACADIA PHARMACEUTICALS
3	Nuplazid	4 Day	NA	NA				ACADIA PHARMACEUTICALS
4	Nuplazid	4 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â Version: 19.0)	ReC
Arrhythmia	NA
Arteriosclerosis	NA
Cardiac arrest	NA
Coronary artery occlusion	NA
Hypertension	NA

Hypertensive angiopathy	NA
Peripheral arterial occlusive disease	NA
Somnolence	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000024), originating in the United States was received from a company representative and from a nurse on 20JUN2016 and from a consumer on 23JUN2016. The report concerned the fatal events of cardiac arrest, coronary artery disease, coronary artery occlusion, peripheral arterial occlusive disease and hypertension and the non-serious event of sleepiness in a 73 year-old female receiving treatment with Nuplazid (pimavanserin). Follow-up was received on 15JUL2016 from physician. Follow-up was received on 15SEP2016 from the physician.

The indication for pimavanserin was Parkinson's disease psychosis with hallucinations and delusions (date of diagnosis was not provided). Medical history included hypertension (well controlled), dry eyes, dementia, orthostatic hypotension (drops 30 points when changing positions), gastroparesis, gait abnormality (ambulated with walker), urinary incontinence, spasticity of neck, migraines (previously treated with Botox injections), colitis, digestive issues, could not urinate (had to be catheterized, had Botox injected in her bladder) and was a resident at a long-term care facility. The patient had no history of coronary artery disease. Patient was allergic to Augmentin, codeine and Reglan. Concomitant medications included: Sinemet (carbidopa, levodopa), Aspirin (acetylsalicylic acid), Altace (ramipril), Depakote (valproate semisodium), Ellura (cranberry), midodrine, Miralax (macrogol), Razadyne (galantamine hydrobromide), Motilin (domperidone), ginger root and Synthroid (levothyroxine sodium).

On 16JUN2016, the patient commenced treatment with pimavanserin 34 mg orally daily. In contrast to the information provided by the nurse, the patient's husband reported the patient started pimavanserin at 2 tablets (34 mg) daily on 15JUN2016 and the dose was decreased to one tablet (17 mg) daily, a day later on 16JUN2016 for an unknown reason. In contrast to previous information the physician reported the patient was started on 17 mg dose on 15JUN2016.

On (b) (6) a nurse went into the patient's room at 6 am to give her dose of Synthroid and the patient ambulated to the bathroom at that time. She was "sleepy" when rounds were performed at 07:55 am. The patient was later found unresponsive without a pulse. CPR was initiated immediately and a full code was performed. EMS arrived and continued CPR. At 8:34 am the patient was pronounced dead. She was not transported to the hospital. The patient's husband paid for an autopsy with his own money. The autopsy reported the cause of death as primary cardiac arrest due to coronary arterial disease, hypertension, 60% restriction in the artery and PAD (peripheral

arterial disease). The cause of death was confirmed by physician as coronary arterial disease (CAD).

The autopsy report was provided upon follow-up. The cause of death per autopsy report was atherosclerotic and hypertensive cardiovascular disease with terminal/fatal arrhythmia. Idiopathic Parkinson's disease was considered a contributing factor. The autopsy pathological findings included: 1)Atherosclerotic and hypertensive cardiovascular disease. Moderate to marked, 2 vessel coronary artery disease. Slight cardiomegaly (386 grams) with bi-ventricular dilatation, heart with left ventricular hypertrophy (1.6 cm thick). Kidneys with moderate arteriolar nephrosclerosis. Consistent with sudden terminal fatal cardiac arrhythmia. Status post terminal resuscitation with rib fractures. No evidence of CHF or brain infarction. 2) History of neurodegenerative disease for years; Parkinson's disease with psychosis and questionable dementia, recently added Nuplazid for PDP, brain with slight diffuse atrophy (1,186 grams) Substantia nigra with marked depigmentation and gliosis. Histopathology report consistent with idiopathic Parkinson's disease, no evidence of Alzheimer's or Lewy body dementia.3) Chronic obstructive pulmonary disease (moderate emphysema) 4) No evidence of pneumonia, sepsis, pulmonary emboli or brain infarctions. Internal examination of cardiovascular system showed: pericardial sac unremarkable, normal distribution of right predominant coronary arteries. The proximal segment of the left anterior descending coronary artery has 80-90 % occlusion. The proximal and mid segments of the right coronary arteries have 60-70 % atherosclerotic occlusion. The remaining coronary arteries are relatively unremarkable. No recent or healing coronary artery thrombus. The myocardium is homogeneous, dark-red and firm without pallor, hemorrhagic infarction or softening. Both ventricles have moderated dilation. The left ventricular wall is 1.6 cm, the inter-ventricular septum is 1.5 cm and the right is 0.5cm thick. The endocardial surfaces and 4 cardiac valves are unremarkable. The aorta has moderate atherosclerosis with focal ulcers and calcification. The pulmonary vessels have slight atherosclerosis. The venae cavae and pulmonary arteries are without thrombus or embolus.

The initial reporter did not assess the causality of events in relationship to pimavanserin. The patient's husband does not believe that the events are the cause of death. "He thinks Nuplazid contributed to her death." He believes "60% restriction does not cause death, and claims people with 80% restriction are walking around". The physician confirmed that the patient's death was not related to Nuplazid. Upon follow-up the physician did not assess the causal relationship of the events atherosclerotic cardiovascular disease, hypertensive cardiovascular disease and fatal arrhythmia in relation to pimavanserin.

The above is a revised narrative incorporating the follow-up received on 15JUL2016. The following new information was added: Confirmation of the cause of death and causality.

The above is a revised narrative incorporating follow-up information received on 15SEP2106. The following new information was added: additional medical history, start dose of pimavanserin, and autopsy report with additional

Case ID: 12507321

causes of death.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Colitis			
Dementia			YES
Drug hypersensitivity			
Dry eye			
Dyspepsia			YES
Dysuria			
Gait disturbance			YES
Hypertension			YES
Impaired gastric emptying			YES
Living in residential institution			YES
Migraine			YES
Muscle spasticity			
Orthostatic hypotension			YES

Case ID: 12507321

Urinary incontinence

Walking aid user YES

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Pathology test					Y
Electrocardiogram					Y
Electrocardiogram					Y
Electrocardiogram					Y
Autopsy					Y

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Altace			UNK dose, for many years	Hypertension			
2	Aspirin			UNK	Product used for unknown indication			
3	Depakote	125 MG/		125 mg, UNK	Migraine			
4	Ellura	36 MG/		36 mg, UNK	Urinary incontinence	2016		
5	Ginger			UNK	Product used for unknown indication			
6	Midodrine			UNK	Orthostatic hypotension			
7	Miralax			UNK	Product used for unknown indication			
8	Motilin			UNK, for 10 years	Dyspepsia			
9	Razadyne	4 MG/		4 mg, UNK	Memory impairment			
10	Sinemet			UNK	Parkinson's disease			
11	Synthroid			UNK	Product used for			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12507321

Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
				unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12647166

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 04-Aug-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 30-Sep-2016 **Mfr Rcvd Date:** 21-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000309 **Application #:** 207318

Patient Information:

Age: 68 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/		34 mg, qd	Parkinson's disease psychosis	Jul-2016	
2	Nuplazid					Delusion		
3	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid		NA	NA				ACADIA PHARMACEUTICALS
2	Nuplazid		NA	NA				ACADIA PHARMACEUTICALS
3	Nuplazid		NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Death	NA

Case ID: 12647166

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000309), originating in the United States was received from a consumer on 05AUG2016. The report concerned the death of a 68 year-old male patient who was receiving treatment with Nuplazid (pimavanserin). Follow-up was received from a nurse on 21SEP2016.

The indication for pimavanserin was Parkinson's disease psychosis with associated hallucination and delusion. Medical history was not provided. Concomitant medication included acetaminophen (paracetamol), carbidopa/levodopa, glycerin (carbozimethucellulose), docusate sodium, Aricept (donepezil hydrochloride), Avodart (dutasteride), melatonin, memantine, mupirocin calcium, polyethylene glycol, Seroquel (quetiapine fumarate), Zantac (ranitidine hydrochloride), Xarelto (rivaroxaban), Zocor (simvastatin), Flomax (morniflumate), Restoril (tamazepam), and Effexor XR (Venlafaxine hydrochloride).

On an unspecified date in JUL2016, the patient commenced treatment with pimavanserin 2 tablets orally once daily.

The patient received a pimavanserin shipment on 15JUL2016. On (b) (6) the patient passed away. The cause of death is unknown. The patient was under care at a nursing home at the time of his death. In follow-up information received it was reported that the patient's physician did not know the history of his present illness related to his death or the circumstances surrounding it.

The initial reporter did not provide a causality assessment in relation to pimavanserin. Causality of the event in relationship to pimavanserin was unknown by the patient's physician.

The above is a revised narrative incorporating the additional information received on21SEP2016. The following was added: Information that the patient was under care at a nursing home and physician causality assessment.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12647166

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Acetaminophen			600 mg	Product used for unknown indication			
2	Aricept				Product used for unknown indication			
3	Avodart				Product used for unknown indication			
4	Carbidopa/Levodopa			25/100	Product used for unknown indication			
5	Docusate calcium				Product used for unknown indication			
6	Effexor XR			150 mg	Product used for unknown indication			
7	Flomax			0.4 mg	Product used for unknown indication			
8	Melatonin			10 mg	Product used for unknown indication			
9	Memantine				Product used for unknown indication			
10	Mupirocin calcium				Product used for unknown indication			
11	Polyethylene glycol				Product used for unknown indication			
12	Restoril			30 mg	Product used for unknown indication			
13	Seroquel			50 mg UNK	Product used for unknown indication			
14	Xarelto			20mg	Product used for unknown indication			
15	Zantac			150mg	Product used for unknown indication			
16	Zocor			40 mg	Product used for unknown indication			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12647166

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12663744

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 25-Jul-2016 **Outcomes:** DE,HO, **Application Type:** NDA

FDA Rcvd Date: 29-Sep-2016 **Mfr Rcvd Date:** 20-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000232 **Application #:** 207318

Patient Information:

Age: 74 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	23-Jul-2016	2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	57 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Agitation	NA
Aortic rupture	NA
Confusional state	NA
Death	NA
Paranoia	NA
Peripheral swelling	NA

Case ID: 12663744

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000232), originating in the United States was received from a patient's son on 26JUL2016. The report concerned the non-serious events of lower leg swelling, agitated, paranoid and confused in a 74 year-old male patient receiving treatment with Nuplazid (pimavanserin). Follow up was received from a registered nurse on 06SEP2016, which upgraded the case to serious. Follow up information was received on 20SEP2016.

The indication for pimavanserin was Parkinson's disease associated with psychosis. Medical history was not provided. Concomitant medications includes: clopidogrel bisulfate, meloxicam, metoprolol tartrate, oxybutynin hydrochloride, ramipril, ropinirole hydrochloride, simvastatin, vitamin B complex, Vitamin D3 (colecalciferol), acetaminophen, carbidopa, lidocaine, and Aspirin (acetylsalicylic acid).
.
On 23Jul2016, the patient commenced treatment with pimavanserin 34 mg orally once daily.

It was reported that the patient had been on Nuplazid for 4 days, he lives in a care center. It was reported that the patient tolerated the product well on the first 2 days. The third day the patient had some slight lower leg swelling (25JUL2016), and overnight (into day 4 on 26JUL2016) he called his son in the middle of the night very agitated, and confused. On 26JUL2016, the patient's son was called about his father becoming very paranoid today. The patient's son planned to speak to neurologist on whether to continue Nuplazid or not. Additional information received stated that the patient had a Torn Aorta and was hospitalized. Exact date was unknown. The physician is aware and pimavanserin was on hold. On 20SEP2016, it was reported that the patient is deceased. The patient passed away on (b) (6) the cause of death was not reported.

The outcome of the events torn aorta, agitation, paranoia, leg swelling and confusion was unknown.

The reporter did not provide a causality assessment for the events in relation to pimavanserin.

The above is a revised narrative incorporating the additional information received on 06SEP2016. The following was added: A new serious event Aortic rupture and patient was hospitalized. Pimavanserin therapy on hold, and concomitant medications added.

The above is a revised narrative incorporating the additional information received on 20SEP2016. The following was added: new event of death, and action taken with Nuplazid.

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12663744

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Acetaminophen			UNK	Product used for unknown indication			
2	Aspirin	81 MG/		81 mg, UNK	Product used for unknown indication			
3	Carbidopa				Product used for unknown indication			
4	Clopidogrel bisulfate				Product used for unknown indication			
5	Lidocaine				Product used for unknown indication			
6	Meloxicam				Product used for unknown indication			
7	Metoprolol tartrate				Product used for unknown indication			
8	Oxybutynin hydrochloride				Product used for unknown indication			
9	Ramipril				Product used for unknown indication			
10	Ropinirole hydrochloride				Product used for unknown indication			

Case ID: 12663744

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
11	Simvastatin				Product used for unknown indication			
12	Vitamin b complex				Product used for unknown indication			
13	Vitamin d3				Product used for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12703541

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 24-Aug-2016 **Outcomes:** DE,HO, **Application Type:** NDA

FDA Rcvd Date: 31-Aug-2016 **Mfr Rcvd Date:** 24-Aug-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000487 **Application #:** 207318

Patient Information:

Age: 67 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Unknown	34 mg, qd	Parkinson's disease psychosis	Aug-2016	Aug-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid		Unk	Unk				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Pneumonia aspiration	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000487), originating in the United States was received from a nurse practitioner on 24AUG2016. The report concerned the serious event of aspiration pneumonia in a 67 year-old male receiving treatment with Nuplazid (pimavanserin).

The indication for pimavanserin was Parkinson's disease psychosis. Medical history and concomitant medications were not provided.

On an unspecified date in AUG2016, the patient commenced treatment with pimavanserin 34 mg orally once daily.

On (b) (6) the patient died of aspiration pneumonia. He was in the hospital prior to his death. Nuplazid therapy was ongoing at the time of death. He was on Nuplazid for one week. No additional AE information was provided.

Case ID: 12703541

The outcome of the event for aspiration pneumonia was fatal.

The reporter did not assess the causality of event in relation to pimavanserin.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ACADIA PHARMACEUTICALS **503B Compounding Outsourcing Facility?:**

Case ID: 12703541

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12703552

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** Jul-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 11-Oct-2016 **Mfr Rcvd Date:** 26-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000301 **Application #:** 207318

Patient Information:

Age: 74 YR **Sex:** Female **Weight:** KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg qd	Parkinson's disease psychosis	05-Jul-2016	23-Aug-2016
2	Nuplazid					Delusion		
3	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	50 Day	NA	NA				ACADIA PHARMACEUTICALS
2	Nuplazid	50 Day	NA	NA				ACADIA PHARMACEUTICALS
3	Nuplazid	50 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Death	NA
Dysphagia	NA
Eating disorder	NA

Case ID: 12703552

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000301), originating in the United States was received from a patient's husband on 04AUG2016. The report concerned the non-serious events of experiencing difficulty in swallowing and stopped eating and drinking in a 74 year-old female receiving treatment with Nuplazid (pimavanserin). Follow-up received from a consumer on 25AUG2016. Non-significant follow-up received on 21SEP2016. The physician's office was contacted on 26SEP2016, patient was confirmed, and office will foward us additional info. However no new safety information was received at this time. Follow up information received from the physicians office on 26SEP2016.

The indication for pimavanserin was Parkinson's disease psychosis with associated hallucinations and delusions. Medical history included: severe dementia, seizure disorder and drug allergy to tetracycline and Vicodin. Concomitant medications included: Parcopa (carbidopa, levodopa), Seroquel (quetiapine fumarate), Exelon Patch (rivastigmine), Namenda (memantine hydrochloride), Lamotrigine taken for seizure disorder, Zoloft (sertraline hydrochloride), Norvasc (amlodipine besilate), Ecotrin (acetylsalicylic acid), Lipitor (atorvastatin calcium), Calcium carbonate and vitamin d (calcium carbonate, colecalciferol), Colace (docusate sodium) taken for constipation, Flonase (fluticasone propionate), Klor-con (potassium chloride), Zofran (ondansetron) taken for nausea and Fibercon (polycarbophil calcium)..

On 05JUL2016, the patient commenced treatment with pimavanserin 34 mg once daily.

On an unspecified date in JUL2016, since starting pimavanserin the patient's husband reported that his wife is now at hospice-assisted living. He stated his wife had been experiencing difficulty in swallowing while on Nuplazid. He doesn't want to get her off of it. Within last week or so she stopped eating or drinking. It was reported that the difficulty swallowing started about a week ago. It was reported that the patient is still on Nuplazid and that the patient's husband wants her to continue taking the medication. It does not appear that patient's husband believes these events are due to patient taking Nuplazid. The therapy with pimavanserin was ongoing. Additional information states that the patient passed away on (b) (6) MD is aware. Cause of death is unknown. The physician reported that the patient was taking pimavanserin from 05JUL2016-23AUG2016 (previously reported as 28JUL2016-23AUG2016). The physician was unsure as to the reason the patient was in hospice.

The outcome of the event of unknown cause of death was fatal, the outcome of the events of swallowing difficult and stopped eating and drinking was unknown.

The reporter stated causality of initial events not to be related to pimavanserin. The current reporter did not assess the causality as related to pimavanserin. The physician stated causality of death no to be related to pimavanserin.

Case ID: 12703552

The above is a revised narrative incorporating the additional event received on 25AUG2016. The following was added: New event Death due to unknown cause and date of start of therapy.

The above is a revised narrative incorporating the additional information received on 26SEP2016. The following was added: physician causality, medical history, concomitant medications, nuplazid therapy dates, labs, patient height and weight.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Dementia			YES
Drug hypersensitivity			YES
Seizure			
Speech rehabilitation			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Red blood cell count	4.04	10***12/L	3.70	5.10	N
White blood cell count	7.7	10^9/L	4.00	11.00	N
Haemoglobin	12.8	g/dl	12.0	15.0	N
Blood glucose	96	mg/dl	70	139	N
Body temperature	97.6 F (36.4 C)	N/A			N
Red blood cell count	4.68	10***12/L	3.70	5.10	N
Aspartate aminotransferase	21	U/L	10	35	N
Haematocrit	40.2	%	34.0	44.0	N

Case ID: 12703552

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood alkaline phosphatase	123	U/L	35	104	Y
Haemoglobin	14.4	g/dl	12.0	15.0	N
White blood cell count	9.06	10^9/L	4.00	11.00	N
Alanine aminotransferase	9	U/L	10	35	Y
Blood pressure measurement	164/91	mmHg			N
Haematocrit	44.9	%	34.0	44.0	Y
Blood bilirubin	0.3	mg/dl	0.2	1.3	N
Heart rate					Y
Blood pressure measurement					N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Calcium carbonate and vitamin d	1 DF/	Oral	1 DF, qd	Product used for unknown indication			
2	Colace	100 MG/	Oral	100 mg, bid	Constipation			
3	Ecotrin	81 MG/	Oral	81 mg, qd	Product used for unknown indication			
4	Exelon Patch	9.5 MG/	Topical	9.5 mg, qd	Product used for unknown indication	28-May-2016		
5	Fibercon	625 MG/	Oral	625 mg, qd	Product used for unknown indication			
6	Flonase	2 DF/	Nasal	2 DF, prn	Product used for unknown indication			
7	Klor-con	8 MEQ/	Oral	8 mEq, bid	Product used for unknown indication	07-Apr-2014		
8	Lamotrigine	300 MG/		300 mg, qd	Seizure	26-Jul-2016		
9	Lipitor	10 MG/	Oral	10 mg, qd	Product used for unknown indication			
10	Namenda	10 MG/	Oral	10 mg, bid	Product used for unknown indication	07-Mar-2016		
11	Norvasc	5 MG/	Oral	5 mg, qd	Product used for unknown indication	27-Jan-2014		
12	Parcopa			25/100 mg q 4 hrs	Product used for unknown indication	07-Mar-2016		
13	Seroquel	50 MG/		50 mg, tid	Product used for	07-Mar-2016		

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12703552

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
					unknown indication			
14	Zofran				Vomiting			
15	Zofran	8 MG/	Oral	8 mg, prn	Nausea			
16	Zoloft	50 MG/	Oral	50 mg, qd at hs	Product used for unknown indication	04-Jan-2016		

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12703553

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 31-Aug-2016 **Mfr Rcvd Date:** 25-Aug-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000511 **Application #:** 207318

Patient Information:

Age: 66 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid			Unknown	UNK	Product used for unknown indication		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid		NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Dysphagia	NA
Eating disorder	NA
Failure to thrive	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000511), originating in the United States was received from a physician on 25AUG2016. The report concerned the serious event of failure to thrive and non-serious event of stopped eating and drinking in a 66 year-old male receiving treatment with Nuplazid (pimavanserin).

The indication for pimavanserin was not provided. Medical history and concomitant medications were not provided.

On an unspecified date in AUG 2016, the patient commenced treatment with pimavanserin, dosage and frequency unknown.

On (b) (6) one of the patient who had taken Nuplazid passed away due to failure to thrive. The patient had stopped eating and drinking. It was unknown if an autopsy was performed.

Case ID: 12703553

The outcome of the event for death is fatal and outcome of event for stopped eating and drinking is unknown.

The physician assessed the causality of events as not related in relation to pimavanserin.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ACADIA PHARMACEUTICALS **503B Compounding Outsourcing Facility?:**

Case ID: 12703553

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12723312

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 31-Aug-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 03-Oct-2016 **Mfr Rcvd Date:** 26-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000570 **Application #:** 207318

Patient Information:

Age: 68 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	02-Aug-2016	2016
2	Nuplazid					Delusion		
3	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	30 Day	NA	NA				ACADIA PHARMACEUTICALS
2	Nuplazid	30 Day	NA	NA				ACADIA PHARMACEUTICALS
3	Nuplazid	30 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Death	NA

Case ID: 12723312

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000570), originating in the United States was received from a consumer on (b) (6) The report concerned the death of a 68 year-old male patient who was receiving treatment with Nuplazid (pimavanserin). Follow up information was received from a physician on 26SEP2016.

The indication for pimavanserin was Parkinson's disease psychosis with associated hallucinations and delusions. Medical history included: Parkinson's diseases, hypertension and hyperlipidemia. Concomitant medications included: Sinemet (carbidopa, levodopa), Rivastigmine (rivastigmine hydrogen tartrate), trazodone hcl, simvastatin, omeprazole, valsartan and ibuprofen.

On 02AUG016, the patient commenced treatment with pimavanserin 17 mg (two tablets) orally daily. The 30 day trial was delivered on 29JUL2016.

On (b) (6) the patient's wife reported that patient was deceased, so will no longer be taking Nuplazid. They think he had a massive heart attack or stroke, but they don't know yet. The cause of death was not provided, patient had just passed away on day of report. The physician reported that patient was living at home with his wife. He dose not know whether patient had heart attack or stroke. There was no treatment medication given to the patient. No autopsy was performed for the patient. The physician reported the cause of death as unknown.

The reporter did not assess the causality of event in relation to pimavanserin. The physician stated the causality as unknown in relation to pimavanserin.

The above is a revised narrative incorporating additional information received on 26SEP2016. The following was added: Medical history, concomitant medications, start date of Nuplazid, Outcome of death, causality and autopsy confirmation.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Hyperlipidaemia			
Hypertension			
Parkinson's disease			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12723312

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Ibuprofen			UNK, prn	Product used for unknown indication			
2	Omeprazole	40 MG/		40 mg, UNK	Product used for unknown indication			
3	Rivastigmine	9.5 MG/		9.5 mg, qd	Product used for unknown indication			
4	Simvastatin	40 MG/		40 mg, UNK	Product used for unknown indication			
5	Sinemet			25/100, tid	Product used for unknown indication			
6	Trazodone hcl	50 MG/		50 mg, nightly	Product used for unknown indication			
7	Valsartan	80 MG/		80 mg, UNK	Product used for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12744948

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 05-Sep-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 21-Sep-2016 **Mfr Rcvd Date:** 14-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000637 **Application #:** 207318

Patient Information:

Age: 70 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	25-Aug-2016	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	12 Day	Unk	Unk				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Death	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000637), originating in the United States was received from a consumer on 09SEP2016 . The report concerned the death of an 70 year-old female patient who was receiving treatment with Nuplazid (pimavanserin). Follow up information was received on 14SEP2016 from a consumer.

The indication for pimavanserin was Parkinson's disease psychosis. Medical history and concomitant medications were not provided.

On 25AUG2016, the patient commenced treatment with pimavanserin 34 mg orally daily.

On (b) (6) the patient died. The cause of death was not reported. The reporter believes patient was taking pimavanserin at the time of death. No further information was provided. The caregiver for the patient called and stated the patient passed away. The start date of pimavanserin was 25AUG2016. No other information was provided.

Case ID: 12744948

The reporter did not provide a causality assessment for the event in relation to pimavanserin.

The above is a revised narrative incorporating additional information was received on 14SEP2016. The following was added: Start date of Nuplazid therapy.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ACADIA PHARMACEUTICALS **503B Compounding Outsourcing Facility?:**

Case ID: 12744948

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12744949

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 02-Sep-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 25-Oct-2016 **Mfr Rcvd Date:** 18-Oct-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000616 **Application #:** 207318

Patient Information:

Age: 67 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	23-Aug-2016	Sep-2016
2	Nuplazid					Delusion		
3	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	11 Day	NA	NA				ACADIA PHARMACEUTICALS
2	Nuplazid	11 Day	NA	NA				ACADIA PHARMACEUTICALS
3	Nuplazid	11 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Myocardial infarction	NA

Case ID: 12744949

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000616), originating in the United States was received from a consumer on 08SEP2016. Additional information was received from the HCP's office - RN on 13SEP2016. The report concerned the serious fatal event of myocardial infarction in a 67 year-old female patient who was receiving treatment with Nuplazid (pimavanserin). Follow-up received on 20SEP2016 from the physician. Follow-up received from the physician on 18OCT2016.

The indication for pimavanserin was hallucinations and delusions associated with Parkinson's disease psychosis. Medical history includes cardiovascular disease not specified, Parkinson's disease, Diabetes Mellitus 2, Dysphagia, Dysphonia, Depression, and Orthostatic hypotension. Concomitant medications includes: Atorvastatin calcium and Plavix (clopidogrel bisulfate).

The patient was given Nuplazid (pimavanserin) samples from the HCP's office on the 23AUG2016. The medication was shipped on 02SEP2016.

It was reported that on (b) (6) the patient had a myocardial infarction, cause of death is cardiac arrest. It has been confirmed that the patient consumed pimavanserin samples. Additional information stated that the patient's condition prior to MI is that she had end stage Parkinson's disease. MI (Myocardial Infarction) was diagnosed at time of death. No EKG's or investigations available. It is unknown if anyone witnessed the MI event.

The reporter did not assess the causality of event in relation to pimavanserin. The physician assessed the causality as related to pimavanserin.

The above is a revised narrative incorporating the additional information received on 20SEP2016. The following was added: Cause of death, Patient consumed Nuplazid, medical history, and causality assessment.

The above is a revised narrative incorporating the additional information received on 18OCT2016. The following was added: Patient's condition prior to death, diagnosis and witness to MI event.

Relevant Medical History:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12744949

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Cardiovascular disorder			YES
Depression			YES
Dysphagia			YES
Dysphonia			YES
Orthostatic hypotension			YES
Parkinson's disease			YES
Type 2 diabetes mellitus			YES

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Atorvastatin				Cardiovascular disorder			
2	Plavix				Cardiovascular disorder			

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12791635

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 17-Sep-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 29-Sep-2016 **Mfr Rcvd Date:** 22-Sep-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000748 **Application #:** 207318

Patient Information:

Age: 68 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		17 MG/	Oral	17 mg, qd	Parkinson's disease	13-Sep-2016	17-Sep-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	5 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Death	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000748), originating in the United States was received from a nurse on 22SEP2016. The report concerned the death of an 68 year-old male patient who was receiving treatment with Nuplazid (pimavanserin).

The indication for pimavanserin was Parkinson's disease. Medical history was not provided. Concomitant medications included Seroquel (quetiapine fumarate), Norco (hydrocodone bitartrate, paracetamol), metformin hydrochloride, Zofran (ondansetron hydrochloride), Artificial tears (hypromellose), Sinemet (carbidopa, levodopa), Depakote (valproate semisodium), Remeron (mirtazapine), Fosamax (alendronate sodium), Wellbutrin (bupropion hydrochloride), Tricor (fenofibrate), Aricept (donepezil hydrochloride), Namenda (memantine hydrochloride), Paxil (paroxetine hydrochloride), omeprazole, Mobic (meloxicam), pyridostigmine bromide, alendronate sodium, fenofibrate, Lasix (furosemide) and Liquid tears (polyvinyl alcohol).

On 13SEP2016, the patient commenced treatment with pimavanserin 17 mg orally once daily.

Case ID: 12791635

On (b) (6) the patient died. The cause of death was not reported. It was unknown if an autopsy was performed. No additional information was provided.

The reporter did not assess the causality of event in relation to pimavanserin.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Alendronate sodium				Product used for unknown indication			
2	Aricept				Product used for unknown indication			
3	Artificial tears				Product used for unknown indication			
4	Depakote				Product used for unknown indication			

Case ID: 12791635

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
5	Fenofibrate				Product used for unknown indication			
6	Fosamax							
7	Lasix				Product used for unknown indication			
8	Liquid tears				Product used for unknown indication			
9	Metformin hcl				Product used for unknown indication			
10	Mobic				Product used for unknown indication			
11	Namenda				Product used for unknown indication			
12	Norco				Product used for unknown indication			
13	Omeprazole				Product used for unknown indication			
14	Paxil				Product used for unknown indication			
15	Pyridostigmine bromide				Product used for unknown indication			
16	Remeron				Product used for unknown indication			
17	Seroquel				Product used for unknown indication			
18	Sinemet				Product used for unknown indication			
19	Tricor				Product used for unknown indication			
20	Wel butrin				Product used for unknown indication			
21	Zofran				Product used for unknown indication			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12791635

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12802572

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 08-Sep-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 10-Oct-2016 **Mfr Rcvd Date:** 04-Oct-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000791 **Application #:** 207318

Patient Information:

Age: 60 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	09-Jul-2016	10-Jul-2016

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid	62 Day	NA	NA				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Version: 19.0)	ReC
Sedation	NA

Event/Problem Narrative:

A spontaneous report (MCN # ACA-2016-000791), originating in the United States was received from a consumer on 27SEP2016. The report concerned the death of an 60 year-old female patient who was receiving treatment with Nuplazid (pimavanserin). Follow-up was received from a consumer on 04OCT2016.

The indication for pimavanserin was Parkinson's disease psychosis. Medical history included Parkinsonism since 5 years. Concomitant medications included Sinemet (carbidopa/levodopa) and Botox (botulinum toxin type a)

On 09JUL2016, the patient commenced treatment with pimavanserin 34 mg orally once daily. The free 30 day trial sent on 08JUL2016.

On 10JUL2016, pimavanserin therapy was stopped. On (b) (6) the patient passed away in her sleep. No autopsy was performed for the patient. The patient was at home during time of her death. No additional information was provided.

Case ID: 12802572

The reporter did not assess the causality of event in relation to pimavanserin.

The above is a revised narrative incorporating additional information received on 04OCT2016. The following was added: Start/stop date of pimavanserin, medical history, concomitant medications, event (sedation), patient's living conditions and autopsy confirmation from physician.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Botox				Product used for unknown indication			
2	Sinemet				Product used for unknown indication			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12802572

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text:

FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Esub Case ID(s) Printed:

12689689

Run by: **STEPPERH**

Date - Time: **28-OCT-2016 08:49 AM**

Total number of cases (Esub): 1

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12689689

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 18-Aug-2016 **Outcomes:** DE, **Application Type:** NDA

FDA Rcvd Date: 05-Sep-2016 **Mfr Rcvd Date:** 26-Aug-2016 **Mfr Control #:** US-ACADIA PHARMACEUTICALS INC.-ACA-2016-000432 **Application #:** 207318

Patient Information:

Age: 75 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Nuplazid		34 MG/	Oral	34 mg, qd	Parkinson's disease psychosis	Aug-2016	18-Aug-2016
2	Nuplazid					Delusion		
3	Nuplazid					Hallucination		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	Nuplazid		Unk	Unk				ACADIA PHARMACEUTICALS
2	Nuplazid		Unk	Unk				ACADIA PHARMACEUTICALS
3	Nuplazid		Unk	Unk				ACADIA PHARMACEUTICALS

Event Information:

Preferred Term (MedDRA Â© Version: 19.0)	ReC
Death	NA

Case ID: 12689689

Event/Problem Narrative:

A spontaneous report (ACA-2016-000432), originating in the United States was received from a consumer on 18AUG2016. The report concerned the event of death in a 75 year-old male receiving treatment with Nuplazid (pimavanserin). Follow up information was received from a consumer on 26AUG2016.

The indication for pimavanserin was Parkinson's disease psychosis with associated hallucinations and delusions. Medical history included Parkinson's disease dementia, REM behavioral role disorder, obstructive sleep apnea, restless leg syndrome, hypersomnia, convergence insufficiency, pseudophakia of both eyes, dry eye syndrome, anxiety, diplopia, brow ptosis, posterior embryotoxin, cataract, heart murmur and atrial fibrillation. Concomitant medications included carbidopa/levodopa, cholecalciferol, Pepcid (famotidine), Folbic (cyanocobalamin, folic acid, pyridoxine hydrochloride), Jevity (electrolytes nos, fatty acids nos, glycine max seed oil, minerals nos, potassium bicarbonate, potassium bitartrate, vitamins nos, zea mays oil), multivitamin and Xarelto (rivaroxaban).

The 30 day trial was delivered on 03AUG2016, on unspecified date in 2016, the patient commenced treatment with pimavanserin 34 mg orally daily.

On (b) (6) the reporter informed that the patient passed away at about 3:00 pm, on (b) (6) The cause of death is unknown.

The above is a revised narrative incorporating additional information received on 26AUG2016. The following was added: medical history and concomitant medications.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Anterior chamber cleavage syndrome			
Anxiety			
Atrial fibrillation			
Binocular eye movement disorder			
Brow ptosis			
Cardiac murmur			
Cataract			

Case ID: 12689689

Diplopia

Dry eye

Hypersomnia

Intraocular lens implant

Parkinson's disease

Parkinson's disease

Rapid eye movement sleep behaviour disorder

Restless legs syndrome

Sleep apnoea syndrome

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Carbidopa/Levodopa			25/100	Product used for unknown indication			
2	Cholecalciferol				Product used for unknown indication			
3	Folbic				Product used for unknown indication			
4	Jevity			1.5 kcal PO	Product used for unknown indication			
5	Multivitamin				Product used for unknown indication			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 12689689

	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
6	Pepcid			20 mg	Product used for unknown indication			
7	Xarelto				Product used for unknown indication			

Reporter Source:

Study Report?: No

Sender Organization: ACADIA PHARMACEUTICALS

503B Compounding Outsourcing Facility?:

Literature Text: