AlphaBeta Pharmaceutical

Ofni Systems Inc.
FDA Facsimile Approval: 03/22/06

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

For use by user-facilities, importers, distributors and manufacturers for MANDATORY reporting

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Mfr Report	AA 2255
UF/Importer Report	
FDA Use Only	

A. PATIENT INFORMATION

1. Patient Identifie -	2. Age at Time of Event:	3. Sex	4. Weight
9182	or 30	☑ Female	125 lbs
In confidence	**Date Of Birth:**	☐ Male	or ____kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☑ **Adverse Event** and/or ☐ **Product Problem** *(e.g. defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*

- ☐ Death: _____ *(mm/dd/yyyy)*
- ☐ Disability or Permanent Damage
- ☑ Life-Threatening
- ☐ Congenital Anomaly/Birth Defect
- ☑ Hospitalization - initial or prolonged
- ☐ Other Serious (Important Medical Events)
- ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of This Report *(mm/dd/yyyy)*
2/1/2006	2/15/2006

5. Describe Event or Problem

The patient displayed discoloration of the skin on the upper half of the body 15 minutes after beginning of test. Patient also exhibited signs of emotional distress with interspersed moments of euphoria. Symptoms would completely disappear after approximately 40 minutes, then reappear at irregular intervals.

6. Relevant Tests/Laboratory Data, Including Dates

EEG, negative, 2/1/2006
BA, .035, 2/1/2006

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

Allergic to several breeds of cats (Tabby, Persian, Couger)
Sensitivity to light and low decibal noise after consumption of alcohol

Submission of a report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event.

C. SUSPECT PRODUCT(S)

1. Nam *(Give labeled strength & mfr/labeler)*

#1 Axaprienette, 200mg, AlphaBeta Pharmaceutical
#2

2. Dose, Frequency & Route Use	3. Therapy Date *(If unknown, give duration) from/to (or best estimate)*
#1 400mg, every 4 hours, oral	#1 1/1/2006 to 2/1/2006
#2	#2

4. Diagnosis for Us *(Indication)*

#1 Low alpha waves
#2

5. Event Abated After Use Stopped or Dose

#1 ☐ Yes ☑ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot	7. Exp. Dat
#1 63A441	#1 6/1/2006
#2	#2

8. Event Reappeared After Reintroduction

#1 ☑ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# or Unique ID

312337.221

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

Irqplacebo, 1/26/2006

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name

3. Manufacturer Name, City and State

4. Model	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Profession ☐ Lay User/Patien
Serial	Other	☐ Other

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?

☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

11. Concomitant Medical Products and Therapy Dat *(Exclude treatment of event)*

E. INITIAL REPORTER

1. Name and Address	Phone
Charles Brown Chief Examiner 1234 Main Street Suite 1000 Raleigh, NC 29799-1234	(919) 555-9292 ext. 13

2. Health Professional	3. Occupatio	4. Initial Reporter Also Sen Report to FDA
☑ Yes ☐ No	Registered Nurse	☐ Yes ☐ No ☑ Unk.

MEDWATCH

3500A Facsimile (3/06) *(continued)* **Page____of___**

FDA USE ONLY

F. FOR USE BY USER FACILITY/IMPORTER (Devices only)

1. Check One
☑ User Facility ☐ Importer

2. UF/Importer Report Number

3. User Facility or Importer Name/Addre

4. Contact Person

5. Phone Number

6. **Date User Facility or Importer Became Aware of Event** *(mm/dd/yyyy)*

7. Type of Report
☐ Initial
☐ Follow-up ____

8. Date of This Report *(mm/dd/yyyy)*

9. **Approximate Age of Device**

10. Event Problem Codes *(Refer to coding manual)*
Patient Code ____ – ____ – ____
Device Code ____ – ____ – ____

11. Report Sent to FDA
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

12. Location Where Event Occurred
☐ Hospital
☐ Home
☐ Nursing Hom
☐ Outpatient Treatment Facility
☐ Other ____ *(Specify)*
☐ Outpatient Diagnostic Facility
☐ Ambulatory Surgical Facility

13. Report Sent to Manufacturer
☐ Yes ____ *(mm/dd/yyyy)*
☐ No

14. Manufacturer Name/Address

G. ALL MANUFACTURERS

1. **Contact Office - Name/Address (and Manufacturing Site for Devices)**
AlphaBeta Pharmaceutical LLC
9999 Highway 77 West
Building 550
Morrisville, NC 27999-3456
USA

2. Phone Number
(919) 555-2345 ex

3. Report Source *(Check all that apply)*
☐ Foreign
☐ Study
☐ Literature
☐ Consumer
☑ Health Professional
☑ User Facility
☐ Company Representative
☐ Distributor
☐ Other:

4. **Date Received by Manufacturer** *(mm/dd/yyyy)*
2/5/2006

5.
(A)NDA # 5633
IND # ____
STN # ____
PMA/510(k) # 442
Combination Product ☑ Yes
Pre-1938 ☐ Yes
OTC Produc ☐ Yes

6. If IND, Give Protocol #

7. Type of Report *(Check all that apply)*
☑ 5-Day ☐ 30-Day
☐ 7-Day ☑ Periodic
☐ 10-Day ☐ Initial
☐ 15-Day ☐ Follow-up # ____

9. Manufacturer Report Number
AA 2255

8. Adverse Event Term(s)
Bluecircle alteration, unsound striation

H. DEVICE MANUFACTURERS ONLY

1. Type of Reportable Event
☐ Death
☐ Serious Injury
☐ Malfunction
☐ Other ____

2. If Follow-up, What Type?
☐ Correction
☐ Additional Information
☐ Response to FDA Request
☐ Device Evaluation

3. Device Evaluated by Manufacturer?
☐ Not Returned to Manufacturer
☐ Yes ☐ Evaluation Summary Attached
☐ No *(Attach page to explain why not)* or provide code ____

4. Device Manufacture Date *(mm/dd/yyyy)*

5. Labeled for Single Use?
☐ Yes ☐ No

6. Evaluation Code *(Refer to coding manual)*
Method ____ – ____ – ____ – ____
Results ____ – ____ – ____ – ____
Conclusions ____ – ____ – ____ – ____

7. If Remedial Action Initiated, Check Type
☐ Recall
☐ Repair
☐ Replace
☐ Relabeling
☐ Other ____
☐ Notification
☐ Inspection
☐ Patient Monitoring
☐ Modification/Adjustment

8. Usage of Device
☐ Initial Use of Device
☐ Reuse
☐ Unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional Manufacturer Narrative** and/or 11. ☐ **Corrected Data**