

# Memorandum



Date: February 11, 2010

HPST

Agenda Item No. 3C

To: Honorable Chairman Dennis C. Moss and  
Members, Board of County Commissioners

From: George M. Burgess  
County Manager

Subject: Resolution Authorizing Miami-Dade County to Execute a Consignment Agreement  
with Bioclon Institute and Rare Disease Therapeutics for Coral Snake Antivenin

## Recommendation

It is recommended that Board of County Commissioners (Board) approve the attached resolution authorizing Miami-Dade County to execute a consignment agreement with Bioclon Institute and Rare Disease Therapeutics Inc. for 1,300 vials of Coralymn, a coral snake antivenin.

## Scope

This item will impact the Miami-Dade Fire Rescue Department (MDFR) and all of the residents of the Miami-Dade County.

## Fiscal Impact/Funding Source

MDFR will charge hospitals, or any other entities requesting the product, for the full cost of the antivenin. This item could have a limited fiscal impact as MDFR is liable for missing or damaged antivenin per the agreement.

## Track Record/Monitor

The Miami-Dade Fire Rescue Department's, Venom Response Bureau Officer in Charge (OIC) will provide oversight of this program.

## Background

The limited supply of coral snake antivenin is a growing concern in Miami-Dade County and throughout the United States. Wyeth Pharmaceuticals, the only company licensed by the United States Food and Drug Administration to produce coral snake antivenin, permanently ceased manufacturing the product in 2006. Since then, life-saving coral snake antivenin has been slowly expiring. This national crisis has a profound impact on a local level since 75-80 percent of coral snake bites occur in Florida, and hospitals and zoos across many states do not have access to this antivenin. Currently, MDFR is the sole provider of coral snake antivenin for the entire country and the United States Armed Forces.

The attached agreement with Bioclon Institute and Rare Disease Therapeutics Inc., the exclusive seller and distributor of Coralymn Antivenin for Bioclon Institute of the United States, allows Miami-Dade Fire Rescue to store 1,300 vials of this coral snake antivenin and to resell them on a consignment basis. By keeping this inventory on a consignment basis, MDFR will be able to deploy antivenin when emergencies arise, recouping the costs of the vials by charging hospitals or any other entities requesting the product. The cost reimbursement to Rare Disease Therapeutics Inc. is \$2,000 per vial, making the consignment cache worth \$2.6 million. Any unused vials will be returned to Rare Disease Therapeutics at no cost to Miami-Dade County.

Alina T. Hudak  
Assistant County Manager



# MEMORANDUM

(Revised)

TO: Honorable Chairman Dennis C. Moss      DATE: March 2, 2010  
and Members, Board of County Commissioners

FROM: R. A. Cuevas, Jr.      SUBJECT: Agenda Item No.  
County Attorney

Please note any items checked.

- "3-Day Rule" for committees applicable if raised
- 6 weeks required between first reading and public hearing
- 4 weeks notification to municipal officials required prior to public hearing
- Decreases revenues or increases expenditures without balancing budget
- Budget required
- Statement of fiscal impact required
- Ordinance creating a new board requires detailed County Manager's report for public hearing
- No committee review
- Applicable legislation requires more than a majority vote (i.e., 2/3's \_\_\_\_, 3/5's \_\_\_\_, unanimous \_\_\_\_ ) to approve
- Current information regarding funding source, index code and available balance, and available capacity (if debt is contemplated) required

Approved \_\_\_\_\_ Mayor

Agenda Item No.

Veto \_\_\_\_\_

Override \_\_\_\_\_

RESOLUTION NO. \_\_\_\_\_

RESOLUTION AUTHORIZING MIAMI-DADE COUNTY TO EXECUTE A CONSIGNMENT AGREEMENT WITH BIOCLON INSTITUTE AND RARE DISEASE THERAPEUTICS FOR 1,300 VIALS OF CORALYMN, A CORAL SNAKE ANTIVENIN

**WHEREAS**, the cache of Coralymn, a coral snake antivenin, has slowly been expiring since Wyeth Pharmaceuticals ceased production in 2006; and

**WHEREAS**, the Miami-Dade Fire Rescue Venom Response Bureau supplies antivenin to hospitals and zoos throughout the United States, and to the United States Armed Forces; and

**WHEREAS**, 75 to 80 percent of the coral snake bites occur in Florida; and

**WHEREAS**, Bioclon Institute makes Coralmyn, a coral snake antivenin; and

**WHEREAS**, Rare Disease Therapeutics, the exclusive seller and distributor of Coralymn Antivenin for Bioclon Institute, has agreed to distribute 1,300 vials of this antivenin to Miami-Dade Fire Rescue (MDFR) on a consignment basis; and

**WHEREAS**, MDFR will charge any party requesting coral snake antivenin for the cost associated with the amount used;

**WHEREAS**, the Board desires to accomplish the purposes outlined in the accompanying memorandum, a copy of which is incorporated herein by reference,

**NOW, THEREFORE BE IT RESOLVED: BY THE BOARD OF COUNTY COMMISSIONERS OF MIAMI-DADE COUNTY, FLORIDA** that Miami-Dade County may execute a consignment agreement with Bioclon Institute and Rare Disease Therapeutics for 1,300 vials, of Coralymn, a coral snake antivenin.

The foregoing resolution was offered by Commissioner  
who moved its adoption. The motion was seconded by Commissioner  
and upon being put to a vote, the vote was as follows:

Dennis C. Moss, Chairman	
Jose "Pepe" Diaz, Vice-Chairman	
Bruno A. Barreiro	Audrey M. Edmonson
Carlos A. Gimenez	Sally A. Heyman
Barbara J. Jordan	Joe A. Martinez
Dorin D. Rolle	Natacha Seijas
Katy Sorenson	Rebeca Sosa
Sen. Javier D. Souto	

The Chairperson thereupon declared the resolution duly passed and adopted this  
2<sup>nd</sup> day of March, 2010. This resolution shall become effective ten (10) days after the  
date of its adoption unless vetoed by the Mayor, and if vetoed, shall become effective  
only upon an override by this Board.

MIAMI-DADE COUNTY, FLORIDA  
BY ITS BOARD OF  
COUNTY COMMISSIONERS

HARVEY RUVIN, CLERK

By: \_\_\_\_\_  
Deputy Clerk

Approved by County Attorney as  
to form and legal sufficiency.

DF.

Daniel Frastai

## CONTINGENCY SALES AGREEMENT

This Contingency Sales Agreement (Agreement) is entered into as of this day November 17, 2009 by and between Rare Disease Therapeutics, Inc. (RDT) with principal offices located at 2550 Meridian Blvd. Ste 150, Franklin, TN 37067, Bioclon Institute S.A. (BIOCLON) with principal offices located at Calzada de Tlalpan #4687, Col. Toriello Guerra. C.P. 14050 Mexico DF, and Miami-Dade County, through Miami-Dade Fire Rescue (MDFR), with principal offices located at 9300 N.W. 41st Street, Miami, FL 33178. RDT, BIOCLON, and MDFR are collectively referred to as the "Parties".

WHEREAS, BIOCLON makes and sells Coralmy<sup>n</sup>®, a snake antivenim, (Coralmy<sup>n</sup>);

WHEREAS, RDT is the exclusive seller and distributor of Coralmy<sup>n</sup> for BIOCLON in the United States;

WHEREAS, RDT distributes and sells Coralmy<sup>n</sup> to MDFR;

WHEREAS, BIOCLON sent a shipment of 1,300 vials of Coralmy<sup>n</sup> directly to MDFR;

WHEREAS, RDT desires MDFR to have access to the supply of Coralmy<sup>n</sup> on a contingency sales basis and to distribute vials of Coralmy<sup>n</sup> to others upon request; and,

WHEREAS, MDFR has the facilities, expertise and licensing to maintain, stock and distribute Coralmy<sup>n</sup>;

NOW, THEREFORE, it is agreed between the Parties as follows:

### 1. TITLE, INITIAL INSPECTION AND DEFECTS

- 1.1. The Parties hereby acknowledge that MDFR received from BIOCLON a shipment of 1,300 vials of Coralmy<sup>n</sup>. BIOCLON currently holds the title for the 1,300 vials of Coralmy<sup>n</sup>.
- 1.2. MDFR and RDT shall not be responsible for the shipping and freight costs incurred to deliver the 1,300 vials of Coralmy<sup>n</sup> to MDFR. BIOCLON shall be responsible for the shipping and freight costs incurred to deliver the 1,300 vials of Coralmy<sup>n</sup> to MDFR.
- 1.3. Upon execution of this Agreement, MDFR shall immediately unpack the 1,300 vials of Coralmy<sup>n</sup> received from BIOCLON. MDFR shall carefully examine each of the 1,300 vials and shall notify RDT of any problems with and/or any defects in the shipment which might be reasonably discovered upon visual inspection of the shipment without unloading the individual vials of Coralmy<sup>n</sup>. Within ten (10) business days of execution of this Agreement, MDFR shall notify RDT of any problems and/or defects by providing an itemized list describing each problem and defect in detail.
- 1.4. BIOCLON will indemnify and hold MDFR and RDT harmless against any lost, damaged and/or defective vials of Coralmy<sup>n</sup> that were delivered to MDFR and set forth in the itemized list of Section 1.3 above. MDFR and RDT shall not be responsible for reimbursing BIOCLON the cost of any such lost, damaged and/or defective vials of Coralmy<sup>n</sup>.
- 1.5. MDFR shall, at the expense of RDT, follow RDT's instructions to return any vials of Coralmy<sup>n</sup> which are defective or not in compliance with any applicable laws and regulations. The remaining supply of Coralmy<sup>n</sup> vials are herein referred to as the "Contingency Supply".

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1.6. BIOCLON shall retain title of the Contingency Supply.

## 2. STORAGE, USE, SALES AND DISTRIBUTION

2.1. MDFR shall store and distribute the Contingency Supply on behalf of RDT in exchange for the purchase and use of vials of Coralmyn from the Contingency Supply on a contingency basis.

2.2. Within five (5) days from each use of Coralmyn from the Contingency Supply by MDFR, MDFR shall notify RDT of the use and the amount of vials used. RDT will then invoice MDFR at a price equivalent to no more than \$2,000 per vial. MDFR shall be responsible for the damage to or loss of Coralmyn from the Contingency Supply which is incurred during handling for MDFR's use. MDFR warrants that it will notify RDT of such damage or loss within five (5) days thereof. RDT will then invoice MDFR at a price equivalent to no more than \$2,000 per vial. MDFR shall pay each invoice within thirty (30) calendar days from date of the invoice. Upon receipt of payment by RDT, MDFR shall have title in the vials specified in the given invoice.

2.3. MDFR shall not alter (except to remove from shipping containers) the product packaging or labeling of any of the 1,300 vials, including those of the Contingency Supply, without prior written consent from RDT.

2.4. MDFR shall, at all times, comply with the information and recommendation communicated in writing by RDT with respect to the storage, handling and shipment of products (including storage of product within the temperature parameters specified by RDT).

2.5. Upon receipt of and pursuant to RDT's instructions, MDFR shall ship via Overnight delivery service, or another suitable shipping company mutually agreed upon, at the expense of RDT, Coralmyn from the Contingency Supply to a customer and/or location as set forth in the instructions. MDFR shall track each shipment and provide the receipt confirmation to RDT. MDFR shall not be responsible for the damage to or loss of the Coralmyn incurred during handling and shipping pursuant to RDT's instructions so long as MDFR immediately notifies RDT of the damage or loss at the time of the damage or loss and provides a written summary detailing how the damage or loss occurred.

2.6. MDFR shall use its best efforts so that vials of Coralmyn having the earliest expiration date are used and/or shipped from the Contingency Supply first.

2.7. Should any vials of the Contingency Supply expire and become unusable, MDFR shall notify RDT of such expired vials within five (5) business days from the discovery of the vials expiration and follow RDT's instructions for disposal. MDFR will not be charged expired vials from the Contingency Supply.

2.8. Upon receipt of payment for a given vial(s) of the Contingency Supply, RDT shall pay BIOCLON in accordance with their established business practices.

2.9. BIOCLON shall not ship or supply further amounts of Coralmyn, in addition to the 1,300 vials, to MDFR without a prior written agreement between the Parties.

## 3. INVENTORY AND REPORTS

3.1. Upon request, MDFR shall allow RDT and/or its representative(s) access to the site where the Contingency Supply is stored for inventory and/or inspection at mutually agreed upon date(s) and time(s).

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- 3.2. MDFR shall maintain detailed inventory records in the form of an electronic database which provides the following:
- 3.2.1. Date of each use of Coralmyn from the Contingency Supply by MDFR followed by the quantity, lot number and expiration date.
  - 3.2.2. Date of each damage to or loss of Coralmyn from the Contingency Supply during handling for MDFR's own use followed by the quantity, lot number and expiration date.
  - 3.2.3. Date of each shipment under Section 2.5 followed by the name of addressee, receipt date, tracking number, and the quantity, lot number and expiration date of the vials shipped but only to the extent permitted by applicable laws and regulations, including but not limited to HIPAA.
  - 3.2.4. Date of each damage to or loss of Coralmyn from the Contingency Supply incurred pursuant to Section 2.5 followed by the quantity, lot number and expiration date.
- 3.3. MDFR shall allow RDT unrestricted access to the inventory records and electronic database of Section 3.2.
- 3.4. MDFR shall within ten (10) business days upon receipt of request(s) by RDT, generate report(s) from the electronic database of Section 3.2 and email the report(s) to RDT at mellis@raretx.com and copy to khare@raretx.com.
- 3.5. On a quarterly basis, MDFR shall inventory the Contingency Supply and provide the results of the inventory including a report generated from Section 3.2 to RDT for billing and reconciliation purposes.

#### **4. REPRESENTATIONS AND WARRANTIES**

- 4.1. The Parties shall not take any action which would likely have a materially adverse effect on the standing of any one or more of the Parties in the industry, including the U.S. Food and Drug Agency (FDA), with respect to consumers of Coralmyn, or both. The Parties shall not take any action which would undermine the image of Coralmyn.
- 4.2. MDFR shall not make any performance claims or engage in any promotional activities with respect to Coralmyn, except for the distribution of product literature prepared by RDT, BIOCLON, or both, and any other activities expressly approved by RDT.
- 4.3. RDT and BIOCLON assure, to the best of their knowledge, that the Contingency Supply complies with all applicable laws, regulations, directives and requirements of FDA. RDT and BIOCLON assure, to the best of their knowledge, that the Contingency Supply complies with all applicable laws, regulations, directives and requirements of FDA. RDT and BIOCLON warrant and represent to MDFR that they have full authority to distribute Coralmyn. RDT and BIOCLON warrant and represent to MDFR that they have full authority to allow MDFR to use and distribute Coralmyn in accordance with the terms of this Agreement so long as MDFR complies with any and all applicable laws and regulations.
- 4.4. MDFR warrants that it has the facilities, expertise and licensing to maintain and distribute Coralmyn in compliance with any and all applicable laws and regulations. MDFR also warrants that it will use, maintain and distribute the Contingency Supply in compliance with any and all applicable laws and regulations.

- 4.5. RDT shall not use the trademark or trade names of Miami-Dade County and MDFR except to the extent necessary for performing the activities specified under this Agreement, complying with any applicable laws and regulations, or both.

## 5. TERM AND TERMINATION

- 5.1. The term of this Agreement shall commence on the execution date of this Agreement and shall expire six (6) months after the depletion of the Contingency Supply.
- 5.2. Any Party may terminate this Agreement for any reason and at any time by providing written notice to the other Parties as specified in Section 8 of this Agreement. The termination shall take effect ninety (90) days after receipt by the Parties of the written notice.
- 5.3. Upon termination or expiration of the Agreement, MDFR shall update the inventory records and electronic database and ensure that such is current as of the date of termination or expiration. Within ten (10) business days of termination or expiration of the Agreement, MDFR shall transfer an electronic copy and a paper copy of the inventory database and other information to RDT.
- 5.4. After receipt of written notice of termination, RDT shall provide MDFR written instructions for shipping the remaining supply of vials from the Contingency Supply to another entity and location. Upon receipt of and in accordance with the written instructions, MDFR shall ship, at the expense of RDT, the remaining vials of Coralmyn from the Contingency Supply no later than the termination date. MDFR shall track the shipment and provide the receipt confirmation to RDT. MDFR shall not be responsible for the damage to or loss of the Coralmyn incurred during handling and shipping pursuant to RDT's instructions so long as MDFR immediately notifies RDT of the damage or loss at the time of the damage or loss and provides a written summary detailing how the damage or loss occurred.

## 6. INDEMNIFICATION

- 6.1. RDT shall, at all times during the term of this Agreement and thereafter, defend, indemnify and hold harmless Miami-Dade County, MDFR and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out any actions taken by RDT pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of MDFR and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by MDFR.
- 6.2. BIOCLON shall, at all times during the term of this Agreement and thereafter, defend, indemnify and hold harmless MDFR and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out of the use of Coralmyn and/or any actions taken by BIOCLON pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of MDFR and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by MDFR.
- 6.3. To the extent allowed by Section 768.28 of the Florida Statutes, MDFR shall at all times during the term of this Agreement and thereafter defend, indemnify and hold harmless RDT and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out of any actions taken by MDFR

pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of RDT and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by RDT.

- 6.4. To the extent allowed by Section 768.28 of the Florida Statutes, MDR shall at all times during the term of this Agreement and thereafter defend, indemnify and hold harmless BIOCLON and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out any actions taken by MDR pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of BIOCLON and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by BIOCLON.
- 6.5. RDT shall, at all times during the term of this Agreement and thereafter, defend, indemnify and hold harmless BIOCLON and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out of any actions taken by RDT pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of BIOCLON and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by BIOCLON.
- 6.6. BIOCLON shall, at all times during the term of this Agreement and thereafter, defend, indemnify and hold harmless RDT and its officers, directors, agents and employees from and against claims, suits, damages, liabilities, cost and expenses, including but not limited to court cost and reasonable attorney's fees, incurred in connection with any third party claim arising out of the use of Coralmyn and/or any actions taken by BIOCLON pursuant to and in accordance with this Agreement except to the extent caused by or based upon (i) the gross negligence or intentional misconduct, as defined by applicable law, of RDT and its officers, directors, agents and/or employees, or (ii) breach of the terms of this Agreement by RDT.

## 7. CONFIDENTIALITY

- 7.1. Subject to Florida's Public Records Law, Chapter 119 of the Florida Statutes, MDR agrees to treat any confidential or proprietary information obtained from RDT that was properly labeled as confidential, and that under Florida law is considered confidential as confidential. MDR's compliance or good faith attempts to comply with this Statute shall not be considered a breach of this Agreement.
- 7.2. Subject to Florida's Public Records Law, Chapter 119 of the Florida Statutes, MDR agrees to treat any confidential or proprietary information obtained from BIOCLON that was properly labeled as confidential, and that under Florida law is considered confidential as confidential. MDR's compliance or good faith attempts to comply with this Statute shall not be considered a breach of this Agreement.
- 7.3. MDR agrees not to disclose any of the RDT's information to any third party without first making reasonable efforts to notify RDT. MDR agrees not to disclose any of the BIOCLON's information to any third party without first making reasonable efforts to notify BIOCLON. Notwithstanding anything to the contrary contained herein, MDR shall be permitted to disclose to potential and existing customers of RDT and/or BIOCLON the relationship between MDR, RDT and BIOCLON as may be required by law.

**8. NOTICE**

- 8.1. Any notice required by this Agreement shall be given by prepaid, first class, certified mail, return receipt requested, or by air courier, hand delivery or facsimile, to the given Party at the following addresses:

Rare Disease Therapeutics, Inc (RDT):

Rare Disease Therapeutics, Inc  
2550 Meridian Blvd, Ste 150  
Franklin, TN 37067  
Attn: Milton H. Ellis  
Facsimile: 615-399-1217

Miami-Dade County through Miami-Dade Fire Rescue (MDFR)

Miami Dade Fire Rescue  
Venom Response Bureau  
9300 N.W. 41<sup>st</sup> Street  
Miami, FL 33178  
Attn: Chief Al Cruz  
Facsimile: 786-336-6871

BIOCLON:

Bioclon Institute S.A. (BIOCLON)  
Calzada de Tlalpan # 4687  
Col. Toriello Guerra  
C.P. 14050 Mexico DF  
Attn: Juan Silanes  
Facsimile:

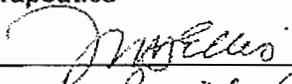
**9. MISCELLANEOUS**

- 9.1. Force Majeure – No liability shall result to any Party from delay in performance or from nonperformance, other than payment of money due hereunder, caused by circumstances beyond the reasonable control of the Party affected, including but not limited to, acts of God, fire, flood, explosion, war, action or request of governmental authority, accidents, labor trouble or shortage, inability to obtain material, power, equipment or transportation, or any other circumstances of a similar or different nature beyond the reasonable control of the Party so failing. The Party suffering the Force Majeure shall diligently attempt to remove such cause or causes and shall promptly notify the other Party of its extent and probable duration.
- 9.2. Governing Law and Venue – This Agreement shall be governed and construed in accordance with the laws of the State of Florida. Exclusive venue for all actions related to this Agreement shall be the state and federal courts located within Miami-Dade County, unless otherwise agreed to the Parties in writing.
- 9.3. Headings – Headings are inserted for the convenience of the Parties only and are not to be considered when interpreting this Agreement. Words in the singular mean and include the plural and vice versa. Words in the masculine mean and include the feminine and vice versa.

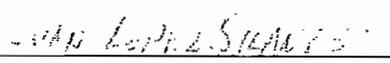
- 9.4. Assignment – No Party may sell, convey, assign, exchange, pledge, encumber, lease or transfer this Agreement or a part thereof to another without the express written consent of the other Party.
- 9.5. Amendments – This Agreement may be amended only by a further written agreement that is duly executed by all Parties.
- 9.6. Severability – Should any provision of this Agreement be or become invalid or unenforceable, then the validity and enforceability of the remaining provisions shall thereby not be affected. The Parties are under the obligation to substitute any invalid or unenforceable provision by a legally effective provision which comes as close as possible to the economic purpose of the invalid or unenforceable provision.
- 9.7. Waiver – The failure of a Party to assert a right to which it is entitled, or to insist upon compliance with any term or condition of this Agreement, shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by another Party.
- 9.8. Entire Agreement – This Agreement constitutes the entire agreement between the Parties with respect to its subject matter and supersedes all proposals, representations, promises, understandings, negotiations and other communications between the Parties, whether written or oral, on the subject matter hereof. Any prior understanding or representation of any kind preceding the date of this Agreement will not be binding on any Party except to the extent incorporated in this Agreement.
- 9.9. The signatories below each warrant that he or she is duly authorized to execute this Agreement.

In witness WHEREOF, the following parties have executed this agreement:

**Rare Disease Therapeutics**

By:   
 Title: President  
 Date: Nov 17, 2009

**Bioclon Institute SA**

By:   
 Title: President  
 Date: Nov. 17, 2009

**Miami-Dade County through Miami-Dade Fire Rescue (MDFR)**

By: \_\_\_\_\_  
 Title: \_\_\_\_\_  
 Date: \_\_\_\_\_