

Memorandum



Date:

To: Honorable Chairman Esteban L. Bovo, Jr.
and Members, Board of County Commissioners

From: Carlos A. Gimenez
Mayor

Subject: Resolution Ratifying the County Mayor's Action of Entering Into a Mosquito
Suppression Services Agreement with MosquitoMate, Inc.



Recommendation

Under authority granted to the Mayor pursuant to Ordinance No.12-92, Section 2.1 of the Miami-Dade County Code, Rules of Procedure, Rule 5.05 (g) Summer Recess Items, it is recommended that the Board of County Commissioners (Board) approve the attached resolution to ratify the County Mayor's action of entering into a Florida Department of Health (FDOH) grant-funded \$4.1 million Mosquito Suppression Services Agreement with MosquitoMate, Inc. (Agreement) and approve the Department of Solid Waste Management's (DSWM) Mosquito Control and Habitat Management Division's (Mosquito Control's) in-kind services to undertake the Miami-Dade County Wolbachia Project (Project).

Scope

The Project will take place in the City of South Miami, pursuant to City Commission Resolution No. 104-17-14905 (attached). If proven effective in Miami-Dade County, *Wolbachia* infected mosquitoes may in the future be used strategically for mosquito suppression countywide.

Fiscal Impact/Funding Source

The Project is funded through a \$4.1 million grant from the FDOH. No County funds will be used for the project; however, Mosquito Control may provide various in-kind services, such as facilitating the placement of mosquito traps and public education and outreach in the City of South Miami.

Track Record/Monitor

The Agreement will be administered by Dr. William Petrie, Division Director, Mosquito Control.

Background

On February 3, 2016, the Florida Department of Health (FDOH) declared a Public Health Emergency for Miami-Dade County due to the spread of the Zika virus. Since then, the Department of Solid Waste Management (DSWM), through its Mosquito Control and Habitat Management Division (Mosquito Control), has partnered with the Florida Department of Agriculture and Consumer Services (FDACS), FDOH, and the U.S. Centers for Disease Control (CDC) to review new and emerging technologies to reduce the *Aedes Aegypti* female mosquito population, the primary vector for disease. This review has included genetically modified mosquitoes, irradiated sterile male mosquitoes, and *Wolbachia* infected male mosquitoes (*Wolbachia*). Of the three emerging technologies, *Wolbachia* has received the most interest and regulatory support. As a result, this technology has been previously deployed in Clovis, California, and the Florida Keys.

Honorable Chairman Esteban L. Bovo, Jr.
and Members, Board of County Commissioners
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Wolbachia treatment focuses on male, non-biting mosquitoes. Wild female mosquitoes that mate with Wolbachia infected males can cause a form of induced sterility in the female's fertilized eggs. As a result, the introduction of Wolbachia infected males can completely eliminate the target mosquito population in a given area. The Miami-Dade County Wolbachia project would involve designating a number of treatment and control areas where surveys of the baseline *Aedes Aegypti* populations would be taken before and after weekly or twice-weekly treatments. Mosquitoes captured in traps subsequent to treatments would be tested for the presence of Wolbachia to ensure the process is working.

Significant progress has been made toward implementing a Wolbachia program in Miami-Dade County during the 2017 mosquito season. On May 16, 2017, the City of South Miami, through Resolution No. 104-17-14905, granted Miami-Dade County the authority to pilot this technology within the city limits of South Miami in 2017-2019 (Attachment A). The U.S. Environmental Protection Agency (EPA) issued Experimental Use Permit No. 89668-EUP-3 to the patent holder, MosquitoMate, for the release of Wolbachia infected mosquitoes in Miami-Dade County through December 31, 2018 (Attachment B). On July 17, 2017, FDACS authorized the experimental use of Wolbachia-infected mosquitoes in Miami-Dade County (Attachment C). FDOH has also approved a Statement of Work for the project with a funding commitment of \$4.1 million through July 31, 2018 (Attachment D), contingent upon Miami-Dade County entering into an agreement with MosquitoMate. As a result of this commitment from FDOH, no County funds will be used for the Wolbachia project; however, Mosquito Control may provide in-kind services such as mosquito trap management and- release of Wolbachia infected mosquitoes.

If proven effective under local conditions in Miami-Dade County, the release of *Wolbachia* infected mosquitoes may be used in the future to control *Aedes aegypti* mosquitoes in areas of prior local Zika virus transmission and areas where conventional control methods are not sufficiently effective.



Alina T. Hudak
Deputy Mayor

RESOLUTION NO. _____

A Resolution accepting the offer by Miami-Dade County to conduct field tests in South Miami of a novel and safe method for controlling the mosquito species that carries Zika.

WHEREAS, the City Commission desires to protect its citizens from mosquito-borne disease; and

WHEREAS, the mosquito borne viruses Zika, Dengue, and Chikungunya have been transmitted by mosquito bites in Miami-Dade County; and

WHEREAS, these diseases are transmitted by the West African mosquito species *Aedes aegypti* that is particularly common in South Miami; and

WHEREAS, the population of *Aedes aegypti* in Miami-Dade County has evolved resistance to many insecticides, including the ones most commonly used to control mosquitoes; and

WHEREAS, a novel and safe method of mosquito control the release of non-biting male mosquitoes that carry *Wolbachia pipientis*, a bacterium that resides only inside the cells of mosquitoes; and

WHEREAS, Miami-Dade County has offered to pay for the releases in South Miami and conduct follow-up studies in cooperation with the Centers for Disease Control (CDC) at no cost to the City of South Miami; and

WHEREAS, experts at the University of Miami's Miller School of Medicine and Florida International University's Dept. of Biological Sciences have reviewed the County's proposal and recommend, with no reservations, that South Miami accept the County's offer; and

WHEREAS, the mosquito season is beginning, Zika is expected to recur in Miami-Dade County this summer, and we have no time to waste.

NOW, THEREFORE, BE IT RESOLVED BY THE MAYOR AND CITY COMMISSION OF THE CITY OF SOUTH MIAMI, FLORIDA, THAT:

Section 1. The City Commission hereby grants Miami-Dade County permission to contract for field releases of non-biting male mosquitoes carrying *Wolbachia pipientis*, and to conduct field studies inside the City limits of South Miami in 2017-2019.

Section 2. This agreement can be cancelled by either party at any time with written notification.

1 **Section 3.** If any section clause, sentence, or phrase of this resolution is for any
2 reason held invalid or unconstitutional by a court of competent jurisdiction, the holding shall not
3 affect the validity of the remaining portions of this resolution.

4
5 **Section 4.** This resolution shall take effect immediately upon adoption.

6
7 PASSED AND ADOPTED this _____th day of _____, 2017.

8
9 ATTEST:

APPROVED:

10
11 _____
12 CITY CLERK

MAYOR

13
14 READ AND APPROVED AS TO FORM,
15 LANGUAGE, LEGALITY,
16 AND EXECUTION THEREOF:

COMMISSION VOTE
Mayor Stoddard:
Vice Mayor Welsh:
Commissioner Edmond:
Commissioner Harris:
Commissioner Liebman:

17
18
19
20
21 _____
22 CITY ATTORNEY
23



Office of the Mayor

10 May 2017

To: Members of the City Commission and City Manager Steven Alexander

From: Philip K. Stoddard, Ph.D., Mayor

Re: Miami-Dade County offer to test mosquito control with a novel and safe method

Miami-Dade County has asked whether South Miami would host the initial 2017-18 field trials of a recently developed method for suppressing populations of *Aedes aegypti*, the mosquito species that can carry and transmit the Zika virus.

The proposed method involves the release of **non-biting** male mosquitoes that mate with the local females, but are rendered reproductively incompatible by a symbiotic bacterium, *Wolbachia pipientis*, residing inside their cells. The resulting eggs fail to hatch, and the mosquito population is reduced. The method is biologically safe. Male mosquitoes subsist on flower nectar and do not bite people or other animals. *Wolbachia pipientis* resides only in the cells of mosquitoes and cannot infect humans or other animals. No transgenic methods are involved.

Under this plan, Miami-Dade County would pay for the releases of non-biting, male mosquitoes with *Wolbachia* and County staff would collect field data to determine the efficacy of this method for reducing the local populations of *Aedes aegypti* mosquitoes.

I sent the County's proposal to two colleagues for their review. Dr. John Beier, is Chief of the Division of Environment & Public Health in the Department of Public Health Sciences at University of Miami's Miller School of Medicine. Dr. Beier is an expert on the control of mosquito-borne disease and serves as Editor of the preeminent scientific journal on disease and public health in the tropics and subtropics. Dr. Matt DeGennaro works in the Department of Biological Sciences at Florida International University and studies the genetic attraction of the *Aedes aegypti* mosquito to humans. Dr. DeGennaro is funded by the Centers for Disease Control to develop methods for controlling Zika in Miami. Both scientists are working with me on a project funded by the Rockefeller Foundation to eliminate Zika from Miami-Dade County. Both Dr. Beier and Dr. DeGennaro have enthusiastically recommend that South Miami steps up to become the first municipality in Miami-Dade County to conduct field trials to determine whether this this safe method of mosquito control can effectively reduce their populations to a level that cannot transmit disease.

I concur with the assessment of these experts. This offer presents only benefits to the residents of South Miami and has the potential to save lives with no downside to our residents. I strongly recommend that South Miami accepts the County's generous offer.

Approved _____ Mayor Agenda Item No.
Veto _____
Override _____

RESOLUTION NO. _____

RESOLUTION RATIFYING THE COUNTY MAYOR'S ACTION OF ENTERING INTO A FLORIDA DEPARTMENT OF HEALTH GRANT-FUNDED \$4,100,000 MOSQUITO SUPPRESSION SERVICES AGREEMENT WITH MOSQUITOMATE, INC. AND APPROVING THE DEPARTMENT OF SOLID WASTE MANAGEMENT'S MOSQUITO CONTROL AND HABITAT MANAGEMENT DIVISION'S IN-KIND SERVICES AS NEEDED, DURING THE BOARD OF COUNTY COMMISSIONERS' 2017 SUMMER RECESS

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

WHEREAS, this Board has adopted Ordinance No. 12-92, authorizing the County Mayor or County Mayor's designee to administer County business during the Board of County Commissioners' annual summer recess as provided therein, and has directed that all actions taken pursuant to such authority be submitted to this Board for ratification at its first regular meeting in October,

NOW, THEREFORE, BE IT RESOLVED BY THE BOARD OF COUNTY COMMISSIONERS OF MIAMI-DADE COUNTY, FLORIDA, that this Board ratifies the County Mayor's action of entering into a Florida Department of Health grant-funded \$4,100,000 Mosquito Suppression Services Agreement with MosquitoMate, Inc., as provided in Attachment 1, and approving the Department of Solid Waste Management's Mosquito Control and Habitat Management Division's in-kind services as needed, during the Board of County Commissioners' 2017 Summer Recess.

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:

Esteban L. Bovo, Jr., Chairman	
Audrey M. Edmonson, Vice Chairwoman	
Bruno A. Barreiro	Daniella Levine Cava
Jose "Pepe" Diaz	Sally A. Heyman
Barbara J. Jordan	Joe A. Martinez
Jean Monestime	Dennis C. Moss
Rebeca Sosa	Sen. Javier D. Souto
Xavier L. Suarez	

The Chairperson thereupon declared the resolution duly passed and adopted this 3rd day of October, 2017. This resolution shall become effective upon the earlier of (1) 10 days after the date of its adoption unless vetoed by the County Mayor, and if vetoed, shall become effective only upon an override by this Board, or (2) approval by the County Mayor of this Resolution and the filing of this approval with the Clerk of the 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. _____

Attachment 1

Mosquito Suppression Services Agreement

This Mosquito Suppression Services Agreement (this "Agreement"), dated as of Aug. 31, 2017 (the "Effective Date"), is by and between MosquitoMate, Inc., a Kentucky corporation, with offices located at 210 Malabu Drive, Lexington, KY 40502 ("MosquitoMate") and Miami-Dade County, a political subdivision of the State of Florida, by and through its Board of County Commissioners, with offices located at 111 NW 1st Street, Miami, FL 33128 ("County" and together with MosquitoMate, the "Parties", and each a "Party").

WHEREAS, MosquitoMate has developed innovative technologies in the area of mosquito control, including through the use of *Wolbachia* IIT ("WBI") and is the exclusive licensee of US Patent No. 7,868,222, filed March 10, 2006, issued January 11, 2011, and assigned to the University of Kentucky Research Foundation; and

WHEREAS, MosquitoMate has the capability and capacity to provide certain mosquito abatement services to reduce, suppress, and locally eliminate *Aedes aegypti* mosquito populations through the use of non-biting male mosquitoes and biopesticide technologies in accordance with MosquitoMate's Governmental Approvals as attached hereto as Exhibit B, including permits issued by the U.S. Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act; and

WHEREAS, the Florida Department of Health ("FDOH") has committed \$4.1 million in grant funding to the County, through the period ending July 31, 2018, for the Miami-Dade County Wolbachia Project ("Project") and all payments to MosquitoMate pursuant to this agreement shall be made only from FDOH provided funds; and

WHEREAS, the County under the supervision and direction of MosquitoMate agrees to provide various in-kind services in support of the Project, including, but not limited to placing and servicing mosquito traps in designated areas and releasing Wolbachia infected male mosquitoes in designated areas; and

WHEREAS, the County desires to retain MosquitoMate to provide the said services, and MosquitoMate is willing to perform such services under the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, MosquitoMate and the County agree as follows:

1. Services. MosquitoMate shall provide to the County the mosquito suppression services (the "Services or Project") set out in the Statement of Work attached hereto as Exhibit A which has been approved by the Florida Department of Health (FDOH) and issued by the County and accepted by MosquitoMate ("Statement of Work").

2. MosquitoMate Obligations. MosquitoMate shall:

2.1 Designate employees or subcontractors that it determines, in its sole discretion, to be capable of filling the following positions:

(a) A primary contact to act as its authorized representative with respect to all matters pertaining to this Agreement (the "**MosquitoMate Contract Manager**").

(b) A number of employees or subcontractors that it deems sufficient to perform the Services set out in each Statement of Work, (collectively, with the MosquitoMate Contract Manager, "**Provider Representatives**").

2.2 Make no changes in Provider Representatives except:

(a) Following notice to the County.

(b) Upon the resignation, termination, death or disability of an existing Provider Representative.

2.3 Maintain throughout the Term of this Agreement, all appropriate federal and state licenses and certifications ("Governmental Approvals") which are required in order for MosquitoMate or its subcontractors to perform the Services.

3. County Obligations. County shall:

3.1 Designate one of its employees or agents to serve as its primary contact with respect to this Agreement and to act as its authorized representative with respect to matters pertaining to this Agreement (the "**County Contract Manager**"), with such designation to remain in force unless and until a successor County Contract Manager is appointed.

3.2 Require that the County Contract Manager respond promptly to any reasonable requests from MosquitoMate for instructions, information or approvals required by MosquitoMate to provide the Services.

3.3 Cooperate with MosquitoMate in its performance of the Services and provide access to County's premises, employees, subcontractors, and equipment as required to enable MosquitoMate to provide the Services.

3.4 Take all steps necessary, including obtaining any required Governmental Approvals or third party consents, to prevent County-caused delays in MosquitoMate's provision of the Services.

4. Method of Payment for Services.

4.1 In consideration of the provision of the Services by MosquitoMate and the rights granted to County under this Agreement, the County shall pay MosquitoMate for the provision of Services related only to the deliverables in the Statement of Work attached hereto as Exhibit A. MosquitoMate agrees and understands that all payments by the County under this agreement shall be made exclusively from and are contingent upon the \$4.1 million in FDOH provided grant funds allocated to this Project.

4.2 Prior to initiating the Project, MosquitoMate shall provide the County with an estimated itemized Project budget based on the deliverables in the Statement of Work for

approval. The approval of the Project budget shall be at the sole discretion of the County. As part of the Project budget, MosquitoMate shall provide unit costs for the various major recurring activities that make up the Project including, but not limited to, releases of Wolbachia infected male mosquitoes and recapture and testing of the introduced males.

4.3 MosquitoMate shall submit invoices and sufficient supporting documentation to the County for payment on a monthly basis for Services performed that are not related to mobilization. MosquitoMate may submit invoices and sufficient supporting documentation to the County for Payment as frequently as weekly for Services performed related to mobilization. Payment to MosquitoMate pursuant to this Section 4 shall constitute payment in full for the performance of the Services. Unless otherwise provided in the applicable Statement of Work, invoices shall be payable within 45 days of receipt by the County.

4.4 The County shall reimburse MosquitoMate for all reasonable expenses incurred in accordance with the Statement of Work, however, MosquitoMate shall not invoice the County for capital equipment purchases.

4.5 At MosquitoMate's request, the County may provide in-kind services including, but not limited to placing and servicing mosquito traps and releasing Wolbachia infected male mosquitoes in designated areas.

4.6 In addition to all other remedies available under this Agreement or at law, MosquitoMate shall be entitled to suspend the provision of any Services if the County fails to pay any fees when due hereunder and such failure continues for 15 days following written notice thereof.

5. Limited Warranty and Limitation of Liability.

5.1 MosquitoMate warrants that it shall perform the Services:

(a) In accordance with the terms and subject to the conditions set out in the Governmental Approvals, the respective Statement of Work and this Agreement.

(b) In a timely, workmanlike, and professional manner in accordance with generally recognized industry standards for similar services.

5.2 MosquitoMate's sole and exclusive liability and the County's sole and exclusive remedy for breach of this warranty shall be as follows:

(a) MosquitoMate shall use reasonable efforts to promptly cure any such breach; provided, that if MosquitoMate cannot cure such breach within a reasonable time (but no more than 30 days) after the County's written notice of such breach, the County may, at its option, terminate the Agreement by serving written notice of termination in accordance with Section 8.2.

5.3 MOSQUITOMATE MAKES NO WARRANTIES EXCEPT FOR THAT PROVIDED IN SECTION 5.1, ABOVE. ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, ARE EXPRESSLY DISCLAIMED.

6. Intellectual Property. All intellectual property rights, including copyrights, patents, patent disclosures and inventions (whether patentable or not), trademarks, service marks, trade secrets, know-how and other confidential information, trade dress, trade names, logos, corporate names and domain names, together with all of the goodwill associated therewith, derivative works and all other rights (collectively, "**Intellectual Property Rights**") in and to all documents, results, work product and other materials that are delivered to the County under this Agreement or prepared by or on behalf of MosquitoMate in the course of performing the Services, including any items identified as such in the Statement of Work (collectively, the "**Deliverables**") shall be owned by MosquitoMate.

7. Confidentiality. From time to time during the Term of this Agreement, either Party (as "**Disclosing Party**") may disclose or make available to the other Party (as "**Receiving Party**"), non-public, proprietary, and confidential information of Disclosing Party ("**Confidential Information**"); provided, however, that Confidential Information does not include any information that: (a) is or becomes generally available to the public other than as a result of Receiving Party's breach of this Section 7; (b) is or becomes available to Receiving Party on a non-confidential basis from a third-party source, provided that such third party is not and was not prohibited from disclosing such Confidential Information; (c) was in Receiving Party's possession prior to Disclosing Party's disclosure hereunder; (d) was or is independently developed by Receiving Party without using any Confidential Information; or (e) is otherwise considered a public record under Florida Law. Receiving Party shall: (x) protect and safeguard the confidentiality of Disclosing Party's Confidential Information with at least the same degree of care as Receiving Party would protect its own Confidential Information, but in no event with less than a reasonable degree of care; (y) to the extent permitted by Florida Law, including Florida's public records laws, not use Disclosing Party's Confidential Information, or permit it to be accessed or used, for any purpose other than to exercise its rights or perform its obligations under this Agreement; and (z) to the extent permitted by Florida Law, including Florida's public records laws, not disclose any such Confidential Information to any person or entity, except to Receiving Party's Representatives who need to know the Confidential Information to assist Receiving Party, or act on its behalf, to exercise its rights or perform its obligations under this Agreement.

If Receiving Party is required by applicable law or legal process to disclose any Confidential Information, it shall, prior to making such disclosure, to notify Disclosing Party of such requirements in an effort to afford Disclosing Party the opportunity to seek, at Disclosing Party's sole cost and expense, a protective order or other remedy.

8. Term, Termination and Survival.

8.1 This Agreement shall commence as of the Effective Date and shall continue thereafter until either the completion of the Services under all Statements of Work or the expiration of FDOH funding, whichever occurs first, unless sooner terminated pursuant to Section 8.2 or Section 8.3.

8.2 Either Party may terminate this Agreement, effective upon written notice to the other Party (the "**Defaulting Party**"), if the Defaulting Party breaches this Agreement, and such breach is incapable of cure, or with respect to a breach capable of cure, the Defaulting Party does not cure such breach within 15 days after receipt of written notice of such breach.

8.3 Notwithstanding anything to the contrary in Section 8.2, MosquitoMate may terminate this Agreement before the expiration date of the Term on written notice if the County fails to pay any amount when due hereunder and such failure continues for 15 days after the County's receipt of written notice of nonpayment.

8.4 Notwithstanding anything to the contrary in this Section, either Party may, upon (60) days written notice to the other Party, terminate this Agreement before the expiration date of the Term. If this Agreement should be terminated as provided under this paragraph, the County will only be required to pay that amount of the fees and expenses actually performed to the date of termination with no payment due for unperformed Services.

8.5 The rights and obligations of the parties set forth in this Section and any right or obligation of the Parties in this Agreement which, by its nature, should survive termination or expiration of this Agreement, will survive any such termination or expiration of this Agreement.

9. Insurance. During the term of this Agreement, MosquitoMate shall, at its own expense, maintain and carry insurance with financially sound and reputable insurers, in full force and effect that includes, but is not limited to, commercial general liability in a sum no less than \$1,000,000 per occurrence, including bodily injury and property damage. Upon the County's request, MosquitoMate shall provide a certificate of insurance evidencing the insurance coverage specified in this Agreement. The certificate of insurance shall name the County as an additional insured. MosquitoMate shall provide 60 days' advance written notice in the event of a cancellation or material change in the insurance policy. Except where prohibited by law, each Party shall require its insurer to waive all rights of subrogation against the other Party's insurers. The County is self-insured and shall provide evidence of self-insurance coverage upon MosquitoMate's request.

10. Mutual Indemnification. To the extent permitted by Florida Law, including Section 768.28 of the Florida Statutes, each party (as "**Indemnifying Party**") shall indemnify and defend the other party and its officers, directors, employees, agents, affiliates, successors, and permitted assigns (collectively, as "**Indemnified Party**") against any and all losses, damages, diminutions in value, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, costs, or expenses of whatever kind, including professional fees and attorneys' fees, that are incurred by Indemnified Party (collectively, "**Losses**"), arising out of any third-party claim.

11. Entire Agreement. This Agreement, in conjunction with the Confidentiality Agreement entered into between the Parties which is fully incorporated herein, and together with any related Statements of Work, exhibits, schedules, attachments and appendices, constitutes the sole and entire agreement of the Parties with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, regarding such subject matter. The Parties acknowledge and agree that if there is any conflict between the terms and conditions of this Agreement and the terms and conditions of any Statement of Work, the terms and conditions of the Statement of Work shall supersede and control.

12. Notices. All notices, requests, consents, claims, demands, waivers and other communications under this Agreement (each, a “**Notice**”, and with the correlative meaning “**Notify**”) must be in writing and addressed to the other Party at its address set forth below (or to such other address that the receiving Party may designate from time to time in accordance with this Section). Unless otherwise agreed herein, all Notices must be delivered by personal delivery, nationally recognized overnight courier or certified or registered mail (in each case, return receipt requested, postage prepaid). Except as otherwise provided in this Agreement, a Notice is effective only (a) on receipt by the receiving Party; and (b) if the Party giving the Notice has complied with the requirements of this Section 12.

Notice to County: Miami-Dade County
111 NW 1st Street, Suite 2900
Miami, FL 33128

Attention: Alina T. Hudak, Deputy Mayor and
Director, Department of Solid Waste
Management

Notice to MosquitoMate:

MosquitoMate, Inc.
210 Malabu Drive
Lexington, KY 40502

Attention: Stephen Dobson, PhD

13. Severability. If any term or provision of this Agreement is found by a court of competent jurisdiction to be invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

14. Amendments. No amendment to or modification of this Agreement is effective unless it is in writing and signed by each Party.

15. Waiver. No waiver by any Party of any of the provisions of this Agreement shall be effective unless explicitly set forth in writing and signed by the Party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof, nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

16. Assignment. Neither Party shall assign or transfer, any of its rights or delegate any of its obligations under this Agreement without the prior written consent of the other Party. Any

purported assignment or delegation in violation of this Section 16 shall be null and void. No assignment or delegation shall relieve any party of any of its obligations under this Agreement.

17. Successors and Assigns. This Agreement is binding on and inures to the benefit of the Parties to this Agreement and their respective permitted successors and permitted assigns.

18. Subcontracting. Neither Party shall subcontract any of its obligations under this Agreement without first providing written notice to the other Party (any such third party, a "Subcontractor"). Should the other party object to the use of the Subcontractor, then within five (5) business days after receipt of notice of the first party's desire to use the Subcontractor, the other party shall object in writing to the use of the Subcontractor and the Subcontractor may not be used. No subcontracting shall relieve any party of any of its obligations under this Agreement.

19. Relationship of the Parties. The relationship between the Parties is that MosquitoMate is an independent contractor. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture or other form of joint enterprise, employment or fiduciary relationship between the Parties, and neither Party shall have authority to contract for or bind the other Party in any manner whatsoever.

20. No Third-Party Beneficiaries. This Agreement benefits solely the Parties to this Agreement and their respective permitted successors and assigns and nothing in this Agreement, express or implied, confers on any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

21. Choice of Law. This Agreement and all related documents are governed by, and construed in accordance with, the laws of the state of Florida, without giving effect to the conflict of laws provisions thereof to the extent such principles or rules would require or permit the application of the laws of any jurisdiction other than those of the Commonwealth of Kentucky.

22. Counterparts. This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together are deemed to be one and the same agreement. Notwithstanding anything to the contrary in Section 12, a signed copy of this Agreement delivered by facsimile, email, or other means of electronic transmission is deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

23. Force Majeure. MosquitoMate shall not be liable or responsible to the County, nor be deemed to have defaulted or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement when and to the extent such failure or delay is caused by or results from acts or circumstances beyond the reasonable control of MosquitoMate including, without limitation, acts of God, flood, fire, earthquake, explosion, governmental actions, war, invasion or hostilities (whether war is declared or not), terrorist threats or acts, riot, or other civil unrest, national emergency, revolution, insurrection, epidemic, lock-outs, strikes or other labor disputes (whether or not relating to either Party's workforce), or restraints or delays affecting carriers or inability or delay in obtaining supplies of adequate or suitable materials, materials or telecommunication breakdown or power outage.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their respective duly authorized officers.

ATTEST:

MosquitoMate, Inc.
A Kentucky Corporation

By: [Signature]
Secretary

By: [Signature]
Stephen Dobson, PhD

[SEAL]

ATTEST:

MIAMI-DADE COUNTY, a political
subdivision of the State of Florida
BY ITS BOARD OF
COUNTY COMMISSIONERS

HARVEY RUVIN

By: [Signature]
Clerk of the Board

By: [Signature]
Carlos A. Gimenez
County Mayor

Approved for Legal Sufficiency by:

[Signature]
Assistant County Attorney

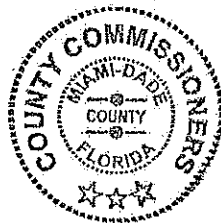


EXHIBIT A
STATEMENT OF WORK

See attached.

EXHIBIT A – MIAMI-DADE COUNTY STATEMENT OF WORK

Release of *Wolbachia*-infected sterile male mosquitoes for population reduction of *Aedes aegypti*

The mosquito control response to the Zika outbreak in Miami-Dade County in 2016 was challenging. The vector, *Aedes aegypti*, breeds in many cryptic habitats in or near human dwellings. Conventional control methods are limited in controlling the vectors under various societal and environmental conditions. The habitats can be difficult to find or access to complete larval control and standing water management. Adult control was limited by widespread resistance to pyrethroid pesticides in the local mosquito population and the urban community had concerns about aerial organophosphate use. In addition, difficulty in timing applications to coincide with periods of peak mosquito activity often limits the effectiveness of aerial adulticiding. New vector control methods that are not dependent upon synthetic adulticide application are needed. Funding will be provided to pilot the use of *Wolbachia*-infected male mosquitoes as part of the comprehensive *Ae. aegypti* vector control response in Miami-Dade county in 2017.

The *Wolbachia*-infected mosquito population reduction intervention is regulated by the Environmental Protection Agency (EPA) and will be implemented under an EPA Experimental Use Protocol (EUP) regulatory mechanism, which is analogous to the use of a drug or vaccine in an emergency situation, under an FDA investigational new drug protocol. While the mechanism carries the term experimental use and certain data is required to be collected by EPA in satisfaction of the statutes associated with this regulatory mechanism, the activity is considered by CDC in its entirety as an emergency intervention to maintain *Ae. aegypti* population levels below the threshold required to support local transmission of Zika virus. This is particularly important to CDC due to the widespread existence of insecticide resistance and the public outcry that occurred last year when synthetic pesticides had to be used to stop the outbreak that was underway in which over 200 cases of Zika infections occurred in Florida. In this context, the intervention is being implemented solely for vector control purposes, and any data that are collected are for the purposes of programmatic/administrative accountability and monitoring purposes, or as required per the conditions of the EUP. Data are not being collected for the purpose of gathering systematic data to generate evidence for the intervention. For this reason CDC does not constitute this to be experimental research but rather emergency response.

Deliverables

1. A mosquito population reduction response plan that outlines, in detail,
 - a. The projected start date, triggers for implementing,
 - b. Geographic areas selected for the intervention.
 - c. Surveillance strategies for
 - i. Baseline *Aedes aegypti* populations in treatment areas,

- ii. Monitoring of mosquito control populations after the release by ovitraps and adult traps
 - iii. Evaluation of the treatment effectiveness (trap results in other compatible areas not using SIT control methods); and
 - iv. Testing of male and female mosquitoes for presence of *Wolbachia*.
2. The plan for:
 - a. The initial mark-release-recapture work to estimate rates of male dispersal and persistence of the introduced males.
3. A copy of the scope of work with the SIT vendor. The scope of work should specify the contractor's responsibilities which include:

Release the *Wolbachia*-infected *Aedes aegypti* male mosquitoes, with the goal of achieving a 7:1 ratio of treated males to wild type males, and monitor the impact of the intervention on the overall *Aedes aegypti* population in a defined geographic treatment area
4. Perform or secure the services of an objective subcontractor to monitor the impact of the intervention on the overall population of *Aedes aegypti* mosquitoes within the treated and an equivalent untreated area, using state-of-the-science mosquito surveillance traps deployed in adequate numbers to ensure data allowing for robust statistical evaluation of the intervention.
5. Maps of treatment/ non-treatment trapping areas. Map showing the distribution of traps by trap type.
6. Weekly reports during the treatment and two weeks post treatment describing
 - a. # of sterile mosquitoes released
 - b. *Aedes aegypti* adult and larval surveillance results in treatment and non-treatment areas, compared to baseline

EXHIBIT B
GOVERNMENTAL APPROVALS

See attached.

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

Celeste Philip, MD, MPH
Surgeon General and Secretary

Vision: To be the Healthiest State in the Nation

July 13, 2017

Carlos A. Gimenez
Mayor of Miami-Dade County
Stephen P. Clark Center
111 N.W. 1st Street, 29th Floor
Miami, Florida 33128

Dear Mayor Gimenez,

I am writing to confirm that Florida Department of Health, through funding from Centers of Disease Control and Prevention, has \$4.1 million set aside to support Miami-Dade Mosquito Control Program's EPA approved release of sterile male mosquitoes infected with Wolbachia. Monthly payments will be provided to the Program throughout the project period as the deliverables in the agreed upon Statement of Work are completed.

Sincerely,

A handwritten signature in cursive script that reads "Carina Blackmore".

Carina G.M. Blackmore, DVM, PhD, Dipl. ACVPM
Director
Division of Disease Control and Health Protection

cc:

RESOLUTION NO. 104-17-14905

A Resolution accepting the offer by Miami-Dade County to conduct field tests in South Miami of a novel and safe method for controlling the mosquito species that carries Zika.

WHEREAS, the City Commission desires to protect its citizens from mosquito-borne disease; and

WHEREAS, the mosquito borne viruses Zika, Dengue, and Chikungunya have been transmitted by mosquito bites in Miami-Dade County; and

WHEREAS, these diseases are transmitted by the West African mosquito species *Aedes aegypti* that is particularly common in South Miami; and

WHEREAS, the population of *Aedes aegypti* in Miami-Dade County has evolved resistance to many insecticides, including the ones most commonly used to control mosquitoes; and

WHEREAS, a novel and safe method of mosquito control the release of non-biting male mosquitoes that carry *Wolbachia pipientis*, a bacterium that resides only inside the cells of mosquitoes; and

WHEREAS, Miami-Dade County has offered to pay for the releases in South Miami and conduct follow-up studies in cooperation with the Centers for Disease Control (CDC) at no cost to the City of South Miami; and

WHEREAS, experts at the University of Miami's Miller School of Medicine and Florida International University's Dept. of Biological Sciences have reviewed the County's proposal and recommend, with no reservations, that South Miami accept the County's offer; and

WHEREAS, the mosquito season is beginning, Zika is expected to recur in Miami-Dade County this summer, and we have no time to waste.

NOW, THEREFORE, BE IT RESOLVED BY THE MAYOR AND CITY COMMISSION OF THE CITY OF SOUTH MIAMI, FLORIDA, THAT:

Section 1. The City Commission hereby grants Miami-Dade County permission to contract for field releases of non-biting male mosquitoes carrying *Wolbachia pipientis*, and to conduct field studies inside the City limits of South Miami in 2017-2019.

Section 2. This agreement can be cancelled by either party at any time with written notification.

Section 3. If any section clause, sentence, or phrase of this resolution is for any reason held invalid or unconstitutional by a court of competent jurisdiction, the holding shall not affect the validity of the remaining portions of this resolution.


Section 4. This resolution shall take effect immediately upon adoption.

PASSED AND ADOPTED this 16th day of May, 2017.

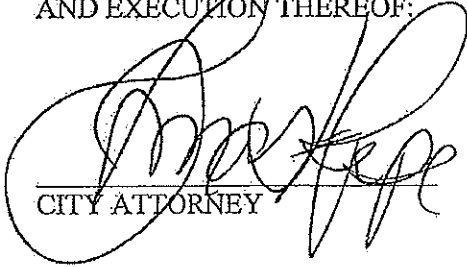
ATTEST:


CITY CLERK

APPROVED:


MAYOR

READ AND APPROVED AS TO FORM,
LANGUAGE, LEGALITY,
AND EXECUTION THEREOF:


CITY ATTORNEY

COMMISSION VOTE	5-0
Mayor Stoddard:	Yea
Vice Mayor Welsh:	Yea
Commissioner Edmond:	Yea
Commissioner Harris:	Yea
Commissioner Liebman:	Yea



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Stephen L. Dobson, Ph.D.
MosquitoMate, Inc.
2520 Regency Road, Suite B
Lexington, KY 40503

Subject: Experimental Use Permit Amendment and Extension for *Wolbachia pipientis*, wAlbB Strain in Male *Aedes aegypti* WB1 Strain Mosquitoes (Including Egg, Larval, Pupal, and Adult Life Stages) in California, Florida, and Texas

Experimental Use Permit No.: 89668-EUP-3

OPP Decision No.: 525795

Effective Dates: Immediately until December 31, 2018 (pesticide applications and associated activities, e.g., collection of field data)

Quantity Authorized: 681,600,000 male *Aedes aegypti* WB1 Strain mosquitoes, weighing 1,610.8 ounces and containing $1,611 \times 10^{-5}$ ounces of active ingredient

Acres Involved: 17,660 acres

Dear Dr. Dobson:

On the basis of the information furnished by you, the subject Experimental Use Permit (EUP) under section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is hereby amended and extended for the pesticidal active ingredient *Wolbachia pipientis*, wAlbB Strain in male *Aedes aegypti* WB1 Strain mosquitoes. The EUP, which is authorized only in the states of California (CA), Florida (FL), and Texas (TX), will evaluate the active ingredient's effectiveness in suppressing and locally eliminating *Aedes aegypti* mosquitoes at particular sites in Fresno County (CA), Orange County (CA), Monroe County (FL), Lee County (FL), Miami-Dade County (FL), and Harris County (TX). Shipment and/or use under this permit are subject to the provisions of 40 CFR Part 172.

Prior to shipment and/or use of this material, you must consult with the pesticide regulatory officials of the states in which you will conduct your experimental program and obtain a state permit or license if such is required. Amendment and extension of this Federal permit does not negate the need for permission from individual states. Prior to initiating this experimental program in any state, you are required to notify the lead agency of the states in which you will conduct your experimental program of the specific testing program (when, where, how much, etc.). Failure to obtain that permission may result in revocation or modification of the EUP.

You must provide notice to the state pesticide regulatory agency at least 72 hours prior to the application of this experimental pesticide product. You must also provide a copy of this authorization letter and the stamped, accepted EUP labeling to all cooperators, participants, and users prior to the initial pesticide application made in accordance with this EUP. The U.S. Environmental Protection Agency (EPA) will notify the relevant EPA Regions of the approval of this EUP by sending copies of this EUP authorization letter and the stamped, accepted EUP labeling to them.

Based on the experimental program submitted, this product may be shipped for use under this EUP to the states of California, Florida, and Texas for the next experimental period, effective immediately until December 31, 2018. The acres and amounts permitted per state are as follows:

STATE	ACRES		NUMBER OF MOSQUITOES		WEIGHT OF MOSQUITOES (OZ)		AMOUNT OF ACTIVE INGREDIENT (OZ)	
	Year 2017	Year 2018	Year 2017	Year 2018	Year 2017	Year 2018	Year 2017	Year 2018
California	2,076	2,076	98,400,000	98,400,000	232.55	232.55	232.6×10^{-3}	232.6×10^{-3}
Florida	3,554	3,554	146,400,000	146,400,000	345.99	345.99	346×10^{-3}	346×10^{-3}
Texas	3,200	3,200	96,000,000	96,000,000	226.88	226.88	226.9×10^{-3}	226.9×10^{-3}
TOTAL	17,660		681,600,000		1,610.8		$1,611 \times 10^{-3}$	

You will immediately notify the EPA of any findings from the experimental uses that have a bearing on safety (i.e., the EPA requires reporting of any adverse effects from the use of or exposure to pesticides). You will also keep records of production, distribution, and performance (e.g., any knowledge of reports indicating that *Wolbachia pipiensis*, wAlbB Strain is occurring in natural populations of *Aedes aegypti*) and make the records available on request to any authorized officer or employee of the EPA.

Prior to registration or amendment under FIFRA section 3, all data requirements must be satisfied (40 CFR Part 158, Subpart V).

The labeling submitted in connection with the application for the EUP is acceptable, and a stamped, accepted copy is enclosed for your records. This labeling must be used for all shipments under this EUP and must be in possession of the user at the time of pesticide application.

You must provide a final report at the conclusion of the experiment. This final report shall include all of the items set forth in 40 CFR § 172.8(b)(2). In addition, you must perform the following testing and monitoring and include the results of this testing and monitoring and other information specified below in the final report:

- (1) Monitor the mosquito population used to produce wAlbB Strain-infected male *Aedes aegypti* mosquitoes for possible infection with pathogenic viruses such as dengue; Zika; Eastern equine encephalitis; vesicular stomatitis; West Nile virus; other arboviruses; and lymphatic, subcutaneous, and serous cavity filariasis.

- (2) Monitor mosquitoes at the release sites to verify the absence of *wAlbB* Strain-infected female *Aedes aegypti* mosquitoes. If polymerase chain reaction (PCR) is used to detect the *wAlbB* Strain, describe how these *wAlbB* Strain-infected female *Aedes aegypti* mosquitoes will be distinguished from the wild female *Aedes aegypti* mosquitoes that have mated with *wAlbB* Strain-infected male *Aedes aegypti* mosquitoes. In other words, describe how you ensure that the wild-type female mosquitoes do not appear *wAlbB* Strain positive (using PCR) after fertilization with *wAlbB* Strain-infected male *Aedes aegypti* mosquitoes.
- (3) Sample released *wAlbB* Strain-infected *Aedes aegypti* mosquitoes to confirm the claimed rate of *wAlbB* Strain-infected female *Aedes aegypti* mosquitoes released.
- (4) Monitor population density of *Aedes aegypti* mosquitoes at the treatment and control sites to determine the impact of *wAlbB* Strain-infected male *Aedes aegypti* mosquito releases and establish the level of *Aedes aegypti* population suppression that can be reached by using a certain male *wAlbB* Strain-infected to male non-infected ratio. Report the abundance of *Aedes aegypti* mosquitoes and other mosquito species captured in the traps at the release sites and the control sites.
- (5) Assess the quality of *wAlbB* Strain-infected male *Aedes aegypti* mosquitoes after shipment by holding a subset in a cage and monitoring survival/fitness over time.
- (6) Record the number of mortality observed for shipments at each release site.
- (7) Mark a subset of *wAlbB* Strain-infected male *Aedes aegypti* mosquitoes to be released with dust and then monitor for their recapture (mark-release-recapture). This addresses questions of the released to indigenous male mosquito ratio and released *wAlbB* Strain-infected male *Aedes aegypti* mosquito survival.
- (8) Collect eggs from the field and record how many are not able to hatch in order to verify a reduction in egg hatch.
- (9) Monitor and record environmental conditions (temperature, wind speed, etc.) from a local National Oceanic and Atmospheric Administration station.
- (10) Provide information as to whether the *Aedes aegypti* mosquitoes treated with tetracycline and then used to create the *wAlbB* lines have been allowed to recover for at least two generations prior to release. Provide information on recolonization of the gut tracts of the tetracycline-cleared mosquitoes with normal resident gut microflora for at least two generations to stabilize the immune systems of the *wAlbB* Strain-infected mosquitoes.

The EPA requests that experiments to determine efficacy of the *Wolbachia pipiensis*, wAlbB Strain in *Aedes aegypti* are designed to assure:

- (1) Control and treatment sites are separated by the appropriate distance, considering the type of habitat (dwellings vs. natural habitat) and available oviposition sites.
- (2) Treatment and control sites occur in the same general suburb with similar characteristics (e.g., socio economic, human density, etc.).
- (3) Unbiased sampling of mosquito eggs and adult females.

The EPA acknowledges that the habitat of *Aedes aegypti* is closely associated with humans and their dwellings. Water-holding containers in urbanized areas provide habitat for the development of larvae; however, other habitats, such as tree cavities, leaf axils of plants, etc., are exploited as well (CDC 2016, <https://www.cdc.gov/dengue/entomologyecology/index.html>).

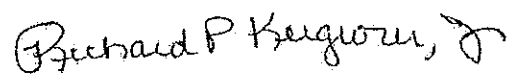
Based on this information, the EPA suggests that:

- (1) The release points also be nearby human dwellings.
- (2) Collections of mosquitoes be conducted in a random and unbiased manner around release points near the dwellings but also extend beyond this likely higher density area to capture efficacy extending into natural habitats (consider typical dispersal distance).
- (3) Ovitrap and BG traps be used to capture data on changes in abundance of viable offspring and adult females.
- (4) The range of activity (area) of the BG traps be reported if this information is attainable and percent reduction of females be measured per effective BG trap area (if possible at this point).
- (5) If the range of the BG traps is unknown and cannot easily be determined, then the percent reduction in females should be reported per treatment site with associated acreage.
- (6) Neighboring treatment areas should be separated by 3 times the typical dispersal distance measuring between release points.

Page 5 of 5
EPA EUP No. 89668-EUP-3
OPP Decision No. 525795

If you have any questions regarding this permit, please contact Wiebke Tapken by phone at (703) 347-0556 or via email at tapken.wiebke@epa.gov.

Sincerely,



Richard P. Keigwin, Jr.
Acting Director
Office of Pesticide Programs

Enclosure

cc: Kimberly Bingham, EPA Region 4 (Florida)
Eugene Thilsted, EPA Region 6 (Texas)
Patti TenBrook, EPA Region 9 (California)

For/To: EPA-OPP-BPPD

Subject: 01/23/2017 draft label for EUP: *Wolbachia pipientis*, wAlbB Strain in Male *Aedes aegypti*, WB1 Strain Mosquitoes (EPA EUP No. 89668-EUP-3 (transferred from former 88877-EUP-2)).

For Experimental Use Only

For use only at an application site of a cooperator or participant and in accordance with the terms and conditions of the Experimental Use Permit. Not for sale to any person other than a participant or cooperator of the EPA-approved Experimental Use Permit program. This label must be in possession of the user at the time of pesticide application. For use only in the states of California, Texas, and Florida.

Read safety directions before using.

Wolbachia pipientis, wAlbB Strain

in male *Aedes aegypti* WB1 strain mosquitoes
EPA Experimental Use Permit No. 89668-EUP-3

ACTIVE INGREDIENT:

Wolbachia pipientis, wAlbB Strain*0.001%

OTHER INGREDIENTS:99.999%

TOTAL:100.000%

*The Active Ingredient is *Wolbachia pipientis*, wAlbB Strain, intracellular, obligate, and naturally-occurring bacteria in male *Aedes aegypti* WB1 strain mosquitoes.

KEEP OUT OF REACH OF CHILDREN

EXPIRATION DATE: PRINT EXPIRATION DATE HERE.

Keep male mosquitoes at moderate temperatures (59°F to 77°F) during delivery and storage.

Lot/Batch No.: _____

Net contents:

Large Unit: A minimum of 0.030 milligrams (mg) *Wolbachia pipientis* wAlbB Strain contained in approximately 15,000 adult *Aedes aegypti* male WB1 Strain mosquitoes weighing 3.54 oz. or 100.50 g maximum weight.

Small Unit: A minimum of 0.002 milligrams (mg) *Wolbachia pipientis* wAlbB Strain contained in approximately 1,000 adult *Aedes aegypti* male WB1 Strain mosquitoes weighing 0.236 oz. or 6.7 g maximum weight. Small Units are transported to the release site inside a styrofoam cooler that has been sealed with tape. The size of the cooler can vary, based on the number of Small Units being transported, e.g., 20 Small Units will fit inside a cooler that is 16x14x13 inches.

EPA Est. Nos.: 89668-KY-001 & 92643-CA-001

MosquitoMate, Inc.
2520 Regency Road, Suite B
Lexington, KY 40503
Phone (859) 488-1125

ACCEPTED

For shipment and use of product for experimental purposes under the provision of the Federal Insecticide, Fungicide, and Rodenticide Act, subject to attached comments.

Permit No. 89668-EUP-3

Issued On 06/22/2017

For/to: EPA-OPP-BPPD

Subject: 01/23/2017 draft label for EUP: *Wolbachia pipientis*, wAlbB Strain in Male *Aedes aegypti*, WB1 Strain Mosquitoes (EPA EUP No. 89668-EUP-3 (transferred from former 88877-EUP-2)).

PRECAUTIONARY STATEMENTS

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

FOR EXPERIMENTAL USE ONLY

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For experimental use by MosquitoMate, Inc.; Verily, LLC; the Consolidated Mosquito Abatement District of Selma and Orange County Vector Control District (CA); Miami-Dade County Department of Solid Waste Management; Lee County Mosquito Control District, Florida Keys Mosquito Control District (FL); and Harris County Public Health, Mosquito and Vector Control (TX); and their cooperators in California, Florida, and Texas under the EPA Experimental Use Permit (EUP) for suppression of *Aedes aegypti* mosquitoes.

Only male (and no female) *Ae. aegypti* strain WB1 mosquitoes carrying *Wolbachia pipientis*, wAlbB Strain microbial pesticide are to be released. The mosquitoes and their life stages are for use only by the staff, technicians, and/or cooperators of MosquitoMate, Inc.; Verily Life Sciences, LLC; the Consolidated Mosquito Abatement District of Selma and Orange County Vector Control District (CA); Miami-Dade County Department of Solid Waste Management; Lee County Mosquito Control District and Florida Keys Mosquito Control District (FL); and Harris County Public Health, Mosquito and Vector Control (TX) specifically trained for this purpose.

Before making the first applications under this EUP, consult with the state agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist. Releases of male mosquitoes are done on a weekly basis with multiple releases per week. Male mosquitoes are released to the air and fly away to mate with indigenous females. The minimum desired ratio of WB1:Wild type male *Ae. aegypti* is a 7:1 ratio. All of the use sites for this EUP are included in Section G of the application (on Field Trial Information Requirements Forms).

Aedes aegypti males that carry *W. pipientis*, wAlbB Strain microbial pesticide are to be released weekly for up to six months in both 2017 and 2018 at the above identified sites. To measure for population suppression effects, mosquito populations will be sampled using mosquito traps to monitor adults and eggs. These mosquitoes typically lay eggs in containers, such as discarded cups or bottles.

At the release site, containers are opened to release adult male mosquitoes that disperse and mate with indigenous *Ae. aegypti* female mosquitoes. WB1 males within large units will be released from a van while driving through the Treated area along public roads. WB1 males within small units will be released by hand at points located throughout the Treated area.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

STORAGE

Keep container closed until ready to use. Keep in original container. Store WB1 males out of direct sunlight and at moderate temperatures 59 °F - 77 °F (15 °C - 25 °C).

PESTICIDE DISPOSAL

Release all living WB1 Males present in container. Discard dead individuals in trash. If WB1 Males are not released by the expiration date, kill males by freezing or allow them to die by

For/to: EPA-OPP-BPPD

Subject: 01/23/2017 draft label for EUP: *Wolbachia pipientis*, wAlbB Strain in Male *Aedes aegypti*, WB1 Strain Mosquitoes (EPA EUP No. 89668-EUP-3 (transferred from former 88877-EUP-2)).

keeping inside closed container for a minimum of 7 days, then discard dead mosquitoes in trash.

CONTAINER HANDLING

Refillable container. Refill this container with WB1 Males (*Wolbachia pipientis*, WB1 strain in *Aedes aegypti*) only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Offer for recycling if available or dispose of in trash or in a sanitary landfill. Do not burn. Cleaning before refilling is the responsibility of the refiller. For cleaning, remove the cap from both ends of the tube, and then use a dry brush to remove any mosquitoes stuck to the inside of the container. Call +1-859-488-1125 for instructions on returning the empty container.

DIVISION OF AGRICULTURAL
ENVIRONMENTAL SERVICES
BUREAU OF PESTICIDES
(850) 617-7917
(850) 617-7949 FAX



THE CONNER BUILDING, No. 6
3125 CONNER BOULEVARD
TALLAHASSEE, FLORIDA 32399-1650

FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
COMMISSIONER ADAM H. PUTNAM

July 17, 2017

Robert Rose, Ph.D.
Regulatory Agent
Mosquito Mate, Inc.
2520 Regency Road
Lexington, KY 40503

SUBJECT: EXPERIMENTAL USE PERMIT EXPANSION AND AMENDMENT
WOLBACHIA PIPIENTIS*, wAlbB STRAIN IN MALE *AEDES AEGYPTI
WB1 STRAIN MOSQUITOES (EPA EUP NO. 89668-EUP-3)
Active Ingredient: *Wolbachia Pipientis*, wAlbB Strain
For evaluation of the active ingredient's effectiveness in suppressing and
eliminating *Aedes aegypti* mosquitoes at particular sites in Lee County,
Miami-Dade County, and Monroe County, Florida.

On the basis of your letter and data submitted, we hereby authorize the distribution and experimental use of the above mentioned product in Florida. This permit has been assigned **EUP NO. 89668-EUP-3** and is authorized through **December 31, 2018**.

The following conditions are placed on this experimental use permit:

- 1) Permittee is responsible for ensuring that distribution and use of this product shall be limited to authorized participants and cooperators. Permittee is also responsible for assuring that all stipulations specified in Rule 5E-2.031, Florida Administrative Code and 40 CFR Part 172 Subpart B are adhered to.
- 2) Permittee certifies that all applications of the subject product will be in accordance with the approved submitted protocol and all applicable directions, restrictions and precautions on the accepted EUP label.
- 3) A copy of this permit, labeling and the experimental protocol must be furnished to, and in the possession of the participant(s) before applications are made.

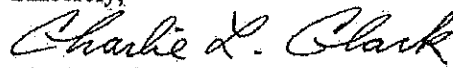
Robert Rose, Ph.D.
July 17, 2017
Page Two

EXPERIMENTAL USE PERMIT; CONT'D

- 4) Specific treatment sites/cooperators must be submitted to the Department prior to initiation of experimentation. The permittee shall inform the department, within 72 hours of application, of the location, time and date of the trials.
- 5) If there are any adverse effects related to the use of this product under this experimental program, the Florida Department of Agriculture and Consumer Services must be immediately notified.
- 6) If experimental trials are not initiated within thirty (30) days of this acceptance letter, the permittee must notify the Department with an update on the protocol program.
- 7) A final report detailing the results of this experimental program must be submitted to this office by **June 30, 2019**.
- 8) Note that although this permit is authorized through **December 31, 2018** all permits and registrations expires biennially on **December 31** and must be renewed by payment of the applicable fees as required under Chapter 487, Florida Statutes. (Note: Federal EUP extension documents must be submitted to FDACS before **December 31, 2018**).

If you should need further clarification or assistance regarding this matter, please contact me at (850) 617-7940.

Sincerely,



Charlie L. Clark
Environmental Administrator
Pesticide Registration Review Section

CLC/sg

Attachment: EUP Label

cc: Dr. Lisa Conti
Mr. Randy Dominy
Mr. Anderson Rackley
Ms. Kelly Friend
Dr. Davis Daiker
Ms. Sarah Oglesby
Ms. Adriane Rogers
Mr. Dale Dubberly
Mr. Neil Richmond
Dr. Lawrence Hribar
Dr. Stephen Dobson
PREC Members