Information Collection Request

Reinstatement with change

Exposure to Aerosolized Brevetoxins During Red Tide Events

Supporting Statement

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A.1 Circumstances Making the Collection of Information Necessary

We are requesting a 3-year approval of this reinstatement request with change of the "Exposure to Aerosolized Brevetoxins during Red Tide Events" OMB package. The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (See Attachment 1). The changes being made to the project since the last clearance are expansion of the research projects to include the following: 1). assessing whether Florida red tide toxins (brevetoxins) induce respiratory symptoms in humans through a direct toxin-mediated effect on cytokines resulting in an inflammatory response, 2). Assessing whether we can detect brevetoxins in nasal exudates, and 3). Assessing whether clinically available drugs, including antihistamines, provide relief for the acute symptoms associated with inhalation of aerosolized brevetoxins.

Background

Karenia brevis (formerly *Gymnodinium breve*) is the marine dinoflagellate that forms extensive blooms (called Florida red tides) in the Gulf of Mexico. G. breve produces potent toxins, called brevetoxins, which have been responsible for killing millions of fish and other marine organisms. All of the U.S. and Mexican Gulf states have experienced extensive red tides that have had adverse impacts on fishing, the quality of the shoreline, and local economies. In addition to killing fish outright, brevetoxins can also become concentrated in the tissues of shellfish when they feed on dinoflagellate. People who eat these shellfish may suffer from neurotoxic shellfish poisoning, a food poisoning that can cause severe gastrointestinal and neurological symptoms.

The human health effects from consuming shellfish with high concentrations of brevetoxins in their tissues have been well documented. However, the biochemical activity of brevetoxins is not completely understood and, while the literature is growing, we do not completely understand the human health effects from environmental exposures. One particular environmental exposure of concern is inhaling brevetoxin that has been aerosolized and swept onto the coast by offshore winds. Anecdotal reports and limited references to human symptoms in the literature (Music et al., 1973; Steidinger and Baden, 1984; Baden 1983) have consistently cited acute respiratory irritation (including nonproductive cough and bronchoconstriction) and burning of eyes, nose, and throat as typical responses from exposure to aerosolized brevetoxins. This is consistent with reports of reversible irritation and bronchoconstriction in asthmatic sheep experimentally exposed to aerosolized brevetoxins (Abraham et al., 2005). Our studies have verified that these respiratory symptoms can be attributed to exposure to aerosolized brevetoxins during Florida red tides (Backer et al., 2005; Fleming et al., 2005). However, we have not been able to identify a biological marker of either exposure or effect. In addition, we have not had a severe red tide since these projects were funded. Thus, we continue to explore the human health effects from environmental exposure to brevetoxins.

<u>Summary of completed studies</u>

We created a team that includes other federal, state, private, and local agencies, i.e.,

Florida Department of Health, Lovelace Respiratory Research Institute, Mote Marine Laboratory, National Institute for Occupational Safety and Health, University of Miami. (see Section A.8.A for list of individuals associated with these health agencies), we have conducted studies to begin to assess the human health consequences of occupational exposure to aerosolized red tide toxins (1998; CDC protocol No. 2805, last continuation approval May 1, 2008). Each group of researchers has been responsible for designing, conducting, and analyzing a specific component of the study, and we have shared data. For example, the team analyzed the concentration of brevetoxins in air and water samples, collected biological samples (nasal and throat swabs) to evaluate as potential markers of exposure and biological effect, collected information about symptoms (using a questionnaire), and assessed respiratory effects in people (using pulmonary function tests, i.e. spirometry).

The respondents for this reinstatement with change (we were unable to submit the revision package in sufficient time for it to be processed before expiration date) are a recruited group of approximately 25 lifeguards (aged ≥18) who work along the coast of Florida and who periodically are occupationally exposed to aerosolized red tide toxins. We have re-contacted previously-enrolled study participants and added additional study participants as new lifeguards were hired in Sarasota through contact with the County Supervisor. For baseline data for these participants we administered a base-line respiratory health questionnaire and conducted pre- and post-shift pulmonary function tests during a time when there is no red tide reported near the area. When a red tide developed, we administered a symptom survey and conducted pulmonary function testing (PFT) on a group of study participants who were working in the area where the red tide was near shore. We then compared 1) symptom reports before and during the red tide and 2) the changes in baseline PFT values during the work shift (differences between pre- and post-shift PFT results without exposure to red tide) with the changes in PFT values during the work shift when individuals are exposed to red tide. In addition we collected biological specimens (inflammatory cells from nose and throat swabs) to assess whether they can be used to verify exposure and to demonstrate a biological effect (i.e., inflammatory response) from exposure to red tide.

Initial data collection activities occurred beginning in September 2001 and have been conducted at various other times since then. A manuscript describing the results of the initial work has been published (Backer et al., 2005). We found that exposures are typically at the limits of our analytic detection methods. We also found that, despite reports of symptoms associated with exposure to aerosolized toxins, the spirometry results do not indicate that there are any significant acute impacts on lung function in healthy individuals. We conducted an additional study to assess whether exercising on the beach would increase exposure by increasing ventilation. Again, we found no changes in pulmonary function associated with exercising during a Florida red tide compared with doing the same exercise activities when there was no Florida red tide. The results of this study are included in the publication mentioned above.

<u>New research activities</u>

Florida red tides are a naturally-occurring event, and we have not had a severe red tide in a number of years. However, when a severe red tide does occur, we plan to respond to collect

additional data from the lifeguards using the original protocol. In addition, we plan to conduct additional research activities as described below.

We are also interested in investigating whether exposure to some component of the red tide-associated toxins elicits an allergic response. Several studies both in animal models and in humans have shown that harmful algal blooms (HABs) cause sinopulmonary symptoms and airway hyperactivity following exposure. It is not known how brevetoxins mediate their sinopulmonary symptoms in humans but the most likely mechanism is through a direct toxin mediated effect inducing inflammatory mediators and cytokines within sinopulmonary tissues.

In collaboration with Dr. Cathy Walsh, Mote Marine Laboratory, Sarasota, Florida, we plan to examine whether these toxins physiologically act to directly induce inflammatory cytokines such as IL8, TNFα and also cause an inflammatory cellular response. We will ask the lifeguards who have participated in other red tide study activities to participate in an additional test (i.e., the collection of nasal exudates) to examine the inflammatory response, the cytokine component of the allergic response to inhaled brevetoxins, and to quantify the amount of brevetoxin that is found in the nose.

Our previous work on Florida red tide has demonstrated that healthy beachgoers and full-time lifeguards experience acute respiratory symptoms after inhaling aerosolized brevetoxins associated with Florida red tides (Backer et al., 2003; Backer et al., 2005). Reported symptoms include upper respiratory irritation (eye irritation, nasal congestion, throat irritation) and lower respiratory irritation (chest tightness, shortness of breath). An additional study conducted with a group of asthmatic volunteers found small but significant changes in pulmonary function (particularly in peak flow) measured using spirometry (Fleming et al., 2005; Fleming et al., 2006).

While conducting our studies on Florida red tide, we have received anecdotal reports that over-the-counter medication intended to relieve symptoms from allergies or nasal congestion relieves the upper respiratory irritation symptoms induced by inhaling aerosolized brevetoxins. In support of these reports, Abraham et al. (2005) reported that, in experiments with asthmatic sheep, bronchoconstriction induced by inhalation of crude cellular extracts containing brevetoxins was relieved by subsequent administration of the β_2 adrenergic agent albuterol, the anticholinergic agent atropine, and the histamine H_2-antagonist diphenhyramine. The sheep were exposed to doses of brevetoxins (ranging from 0.1 pg/mL to 10 pg/mL) at levels that people are likely to experience when visiting beaches during a Florida red tide. Thus, clinically available drugs, including antihistamines, may provide relief for the acute symptoms associated with inhalation of aerosolized brevetoxins.

We propose to add a component to this study to assess whether loratidine, an antihistamine available in over-the-counter products, such as Claritin, can relieve the upper respiratory symptoms induced by inhaling aerosolized brevetoxins during Florida red tides. If this can be demonstrated in a planned study, then public health officials will be able to recommend using over-the-counter medications containing antihistamines to healthy local community members and visitors who experience upper respiratory symptoms when they visit the beaches during a Florida red tide.

Summary

In summary, the purposes of this continuing study is to assess the effects of an over-the counter antihistamine to mitigate the effects of exposure to aerosols containing brevetoxins with the aim to construct a more accurate assessment of exposure to aerosolized red tide toxins and the subsequent health effects. CDC's IRB has approved these studies.

To address the issues discussed above, we plan to continue our work with our occupationally exposed population (lifeguards) over the next three years. The exact timing of the studies will be determined by the occurrence of a substantial red tide off the Sarasota (Florida) coast. Therefore, we are requesting a 3-year approval of this reinstatement request with change of the "Exposure to Aerosolized Brevetoxins during Red Tide Events" OMB package. The data collection authority for this study is Section 301 of the Public Health Service Act (42 USC 241) (See Attachment 1).

Contribution to CDC's research agenda

A critical component of the mission of the National Center for Environmental Health, Centers for Disease Control, is to identify public health impacts from exposures to environmental contaminants. This research agenda will advance our understanding of how the toxins from naturally-occurring Florida red tides impact local communities and will help us determine ways to mitigate those impacts.

Privacy Impact Assessment

Overview of the Data Collection System

The data collection system consists of paper questionnaires as follows: 1). A background health history (done when a participant is recruited into the study), 2). Pre-exposure questionnaires about health symptoms, and 3). Post-exposure questionnaires about health symptoms.

Items of Information to be Collected

Information will be collected from study participants using personal interviews.

Categories of Information in Identifiable Form (IFF) collected are as follows: name, mailing address, phone number.

Additional questionnaire information collected includes a health history with questions about education, asthma, past pulmonary function tests, past and current respiratory symptoms, smoking history, respiratory illnesses (such as bronchitis, hay fever), and history of hospitalization. Other information collected on the symptom surveys includes location of exposure and self-reported presence/absence of respiratory symptoms.

Identifying information is necessary to facilitate the personal contact with respondents required to conduct the survey. However, the identifying information will be left with the Florida DOH and will not be forwarded to CDC. Hard copies of questionnaires used for data entry at CDC will be identified by ID number only.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

We do not plan to host a website for this data collection.

A.2 Purpose and Use of the Information

The purpose of this data collection is to continue our studies of the human health effects from exposure to aerosolized brevetoxins during red tide events. The study will focus on adverse respiratory effects (see Attachments 3 and 4).

The results from this study will be useful to the health agencies in Florida and in other Gulf Coast states that experience human exposures to aerosolized red tide toxins during red tide events. To date, the results from this and other studies have provided information used by Florida Department of Health (FDOH) to create a number of public health information messages. In addition, FDOH has created an automated information hotline that has information about a number of public health issues associated with marine waters, including Florida red tide. Further studies will provide objective information (e.g., PFT results) about the effects of human exposure to the aerosolized toxins that can assist the states in determining whether public health messages should be varied based on the extent of the Florida red tide, i.e., 1) Whether there should be special personal protective equipment for people working on the water during more intense red tides, and 2) Whether there should be additional health hazard warnings on beaches during more intense red tides.

If we do not collect this information, it will severely hamper state-based activities to identify the potential public health hazards from exposure to Florida red tides.

Privacy Impact Assessment Information

IIF such as name, address, and phone number will be collected, along with the personal information regarding each individual's history of respiratory illnesses.

IIF is necessary to facilitate the personal contact with respondents required to conduct the survey. IIF will be left with the Florida DOH and will not be forwarded to CDC. IIF data sharing will be done in accordance with Florida State health department policies and procedures; because the Florida DOH will maintain the link between name and study ID number, CDC will not maintain IIF. Hard copies of questionnaires used for data entry at CDC will be identified by study ID number only.

No highly sensitive information is being collected, so there will be little or no effect on respondents' privacy.

A.3 Use of Improved Information Technology and Burden Reductions

This collection of information will not use automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. The study instruments require collection of only the minimum information necessary for the purposes of the project, thus no improved information technology will be utilized.

A.4 Efforts to Identify Duplication and Use of Similar Information

An extensive review of scientific literature was conducted to locate studies of exposure to brevetoxins and adverse respiratory health outcomes in people that were not done by our research group. We did not identify any other studies. In addition, communication with experts in environmental exposures did not bring to light any similar data collection efforts. No other epidemiologically valid data exists with which to assess the association between occupational exposure to aerosolized brevetoxins and subsequent quantitative and qualitative changes in respiratory health in people.

A.5 Impact on Small Business or Other Small Entities

No small businesses will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

If this data is not collected or is collected less frequently, we will not be able to assess the public health impacts of exposure to Florida red tide aerosols in this population.

Baseline data will be collected one time only for new study participants (data on participants from the earlier study have been kept).

There are no legal obstacles to reduce the burden of this data collection. The number of responses for study participants is described in Table A.12-1.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this data collection. The data collection complies with the guidelines of 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A. A revised 60 Day Federal Register Notice was published in Federal Register Vol. 72, No. 244 / September 10, 2008, pages 52662 – 52663. A copy of the announcement is in Attachment 2.

B. One public response was received (see Attachment 7). No changes were made to the proposed project, as the public comment did not relate to the utility and scope as proposed.

C. The following individuals were consulted to obtain their views on the availability of data, the clarity of instructions, disclosure, and on the data elements to be recorded and reported (see **Section A. JUSTIFICATION)**.

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A.9 Explanation of Any Payment or Gift to Respondents

In our experience with epidemiologic studies, we have found that people are more likely to participate if we offer a cash payment. For this reason, study participants will receive a cash payment of $25 for each day they participate in our study, which will require participation on a total of 4 days. The maximum amount of cash payment any one study participant could receive is $100 (for 4 days of study participation).

A.10 Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Info

A. In the review of this application, it has been determined that the Privacy Act is not applicable. Identifying information (names, etc.) are not sent to CDC; accordingly, CDC data are not retrieved by the name or other identifying particular of the individual; therefore, the data collection does not meet the definition of a Privacy Act system of records. The data will be part of the state's already established record system. The co-principal investigator from the Florida Department of Health (DOH) will keep, in a secure location, study documents containing individual identifiers and the link between name and study id number.

B. IIF will be collected, along with the personal information regarding each individual's history of respiratory illnesses. IIF is necessary to facilitate the personal contact with respondents required to conduct the survey. However, IIF will be left with the Florida DOH and will not be forwarded to CDC. Hard copies of questionnaires used for data entry at CDC will be identified by ID number only.

The paper documents containing personal identifiers will be kept in locked file cabinets

at the Florida DOH, and computer files will be password-protected and access will be limited to authorized study personnel. All staff working on the project will agree to safeguard the data and to not make unauthorized disclosures. Data will be safeguarded in accordance with applicable statutes. Responses in published reports will be presented in aggregate form, and no individuals will be identified by name.

C. Written consent will be obtained from study participants before they participate in any study activities (see Attachment 5: Consent Forms).

D. Participation in the study will be voluntary, as described in the consent forms (see Attachment 5: Consent Forms).

45 CFR 46 (Regulations for Protection of Human Subjects) apply to this project. The protocol has been approved by the CDC Institutional Review Board (Attachment 6).

A.11 Justification for Sensitive Questions

Questions of a highly sensitive nature will not be asked, nor will social security numbers be requested. Questions regarding a diagnosis of respiratory illness may be considered by some respondents to be sensitive, but most people find it innocuous. However, respondents are told that participation in the study is voluntary and they may refuse to answer any of the questions.

OMB considers questions of race/ethnicity to be of a sensitive nature. Studies sponsored by CDC routinely collect this information to assist researchers in translating data from studies into public health practice. Again, respondents are told that participation in the study is voluntary and they may refuse to answer any of the questions.

A.12 Estimates of Annualized Burden Hours and Costs

A.12-1 Estimates of Total Annualized Burden Hour

The burden hours were estimated from the study activities of our field studies. The burden hours have been changed to account for hours used and new hours needed to conduct the studies described above.

Type of Respondent	**Form Name**	**No. of Respondents**	**No. Responses/ Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
New study participants	Pulmonary Health Questionnaire	10	1	20/60	3
Lifeguards (previous participants and new)	Pre- and Post-Shift Red Tide Questionnaire	25	6	5/60	13
	Total				16

A.12-2 Total Annualized Costs to Respondents

The hourly wage rate is $17.91 on average weekly earnings in 2007 in Florida from the

Department of Labor web site at:

https://www.presidentialelection.com/US_Labor_Stats/index_US_Labor_Statistics.htm

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Avg.Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
New study participants	10	1	20/60	3.3	$17.91	$60
All study participants	25	6	5/60	13	$17.91	$233
Total						$293

A.13 Estimates of Other Annualized Respondent Capital and Maintenance Costs

There are no other annualized respondent capital and maintenance costs.

A.14 Estimates of Annualized Cost to the Federal Government

Costs for CDC personnel were estimated based on experience with field studies. We are requesting an additional three years to complete the study.

Item	Total Cost	Annualized Cost
Salary	$ 75,000	$ 25,000
Fringe (20%)	$ 15,000	$ 5,000
Travel	$ 36,000	$ 12,000
Subtotal	$ 126,000	$ 42,000
CDC Administrative (15%)	$ 18,900	$ 6,300
Total	$ 144,900	$ 48,300

A.15 Explanation for Program Changes or Adjustments

This is a reinstatement of a currently approved data collection. We were unable to prepare the revision package in sufficient time for it to be processed before expiration date. The additional hours are needed for further study activities. We have used most of the previously-requested burden hours for various components of the study. We are requesting to use the remainder of the hours to complete the original study and add additional burden hours

to accommodate the new components as described in section A1.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Statistical Analysis Plan

We plan to examine the following spirometry measurements: FEV_1 (forced expiratory volume in the first second); FVC (forced vital capacity), FEV/FVC, and forced expiratory flow for middle half of the spirometry maneuver (FEF 25% - 75%). We also plan to collect nasal exudates on small pieces of filter paper and use these samples to measure cytokine levels, to collect nasal washes to assess brevetoxins levels, and to conduct hearing tests to assess the effects on the central nervous system. We plan to compare pre-shift and post-shift values (symptoms, spirometry parameters, cytokine levels, and hearing test results) for individuals at baseline (when there is no red tide) and during a red tide. We will also compare the changes (post-shift minus pre-shift) in values at baseline with the changes observed during a red tide.

The data collected during the beach survey will be used in conjunction with weather data covering the same time periods to build a model to predict when an on-shore red tide could be expected to produce adverse health effects. This modeling effort will be guided by investigators at Mote Marine Laboratory.

A.16 - 1 Project Time Schedule

A.16 – 1 Project Time Schedule	
Activity	Time Schedule
Baseline data collection for new participants	1.5 – 2.5 months after OMB approval
Exposed and control individuals' data collection during a red tide event	As a red tide develops
Completion of field work	After development of red tide and data collection is complete (potentially 36 months)
Analysis of data	12-18 months after data collection
Publication	24 months after data collection

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

OMB approval to not display the expiration date is not being sought.
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A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Exemption from displaying the expiration date for the OMB approval of forms is not being requested.

There are no exceptions to the certifications.

B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

The target population for this study includes lifeguards who work full time on Florida beaches that are susceptible to red tides.

Individuals have served, and will continue to serve, as their own controls. We will collect baseline information on all newly recruited study participants during a time when there is no red tide exposure.

One of the primary endpoints of interest in this study is the forced expiratory volume in one second (FEV_1) from the spirometry testing. We plan to compare pre-shift and post-shift values for spirometry parameters and cytokines in nasal exudates. We also plan to compare changes in these variables over the shift when study participants are not exposed to aerosolized red tide toxins with the change in these variables over the shift when participants are exposed to aerosolized red tide toxins.

With our past study population of 20 lifeguards, at a significance level (alpha) of 0.05, and 80% power to detect a difference if there is one, we can demonstrate the value of one of our biological markers of exposure or effect if 50% of the participants show a significant change (in cytokine levels, brevetoxin in the nose, etc.) in the biomarker after exposure compared with before exposure (see Cohen, 1988). We expect similar values with our new study population of 25.

In the first phase of this study we have had a 95% response rate (i.e., we asked 21 lifeguards to participate and 20 agreed) for this study.

B.2 Procedures for the Collection of Information

We have collected, and will continue to collect, health information using questionnaires, spirometry, and collection of nasal exudates. First, we administered a baseline pulmonary health history questionnaire (see Attachment 3) based on a survey that was used by the National Institute for Occupational Safety and Health (NIOSH) (OMB number 0920-0350, expiration date 09/30/1997, to assess asthma and other respiratory illnesses in an occupational setting. We will administer this survey to any newly recruited participants.

We will conduct pulmonary function tests using portable spirometry instruments. Spirometry refers to the measurements of exhaled air volume and flow rates from individuals. The important measurements include forced vital capacity (FVC) or the greatest volume of air exhaled from a maximal inspiration to a complete exhalation; the forced expiratory volume in one second (FEV_1) or the volume of air exhaled in the first second of a FVC maneuver; and the ratio between these two values: FEV_1/FVC. The spirometry measurements were made using portable spirometry equipment (the same type used for occupational studies and monitoring), and all procedures will conform to standard guidelines (Standardization of Spirometry - 1994 Update, Am J Respir Crit Care Med, 1995, 152:1107-1136).

During the test, it is critical that participants are properly coached to exert the maximum effort possible. The individuals who administer the spirometry tests were trained to conduct the test and properly coach study participants in a 2-day NIOSH-approved Pulmonary Function Training session.

Pulmonary function testing by spirometry has been, and will continue to be, done before and after the work shift when there is no red tide (baseline data) and again when there is a Florida red tide. Before each spirometry session, study participants will complete the questionnaire asking about current symptoms and times recently spent on or near the shore (see 4).

We also want to know if there is red tide toxin in the air on the beach. To address this question, we will hang personal air samplers on the guard towers near where the lifeguards sit during their shift. We do not ask them to wear the air sampling pump as we are concerned that it might interfere with their activities or that the pump would get wet. The air samples will be analyzed by scientists at Mote Marine Laboratory in Sarasota, Florida.

Quality Control Procedures

The questionnaires are administered by trained interviewers. Data coding and preparation will be done by the principal investigator and a statistician within the Health Studies Branch, NCEH.

B.3 Methods to Maximize Response Rates and Deal with Non-response

In the context of this study, "response rate" is defined as the percentage of selected (by the study criteria) subjects meeting our eligibility criteria who consent to participate and complete the study activities. By recruiting through the Sarasota Parks and Recreation Department, we had a response rate of 95%. We anticipate that the same lifeguards will participate in the studies described in this application. If the response rate is less than anticipated, CDC will request permission from their County-level supervisors to re-approach the life guards to encourage them to continue to be involved.

B.4 Test of Procedures or Methods to be Undertaken

All study materials have been evaluated in pilot tests involving 9 or fewer respondents.

The pilot tests were used to more clearly delineate the recruiting and data collection procedures. All of the questions on the data collection instruments in this package were approved during the original OMB application process for this project.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following individuals were consulted in reviewing the statistical procedures for this study:

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The data collection was designed by the Health Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, CDC, in collaboration with Dr. Lora Fleming, University of Miami School of Medicine.

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Fleming LE, Kirkpatrick B, Backer LC, Bean JA, Wanner A, Dalpra D, Tamer R, Zaias J, Cheng YS, Pierces R, Naar J, Abraham W, Clark R, Zhou Y, Henry MS, Johnson D, Van de Bogart G, Bossart GD, Harrington M, Baden DG. 2005. Initial Evaluation of the Effects of Aerosolized Florida Red Tide Toxins (Brevetoxins) in Persons with Asthma. Environmental Health Perspectives 113-5:650.

Attachments

Attachment 1 Section 301 of the Public Health Service Act (42 USC 241)

Attachment 2 Federal Register Notice

Attachment 3 Pulmonary Health Questionnaire

Attachment 4 Pre- and Post-Shift Questionnaire

Attachment 5 Consent Form

Attachment 6 CDC IRB Approval

Attachment 7 Public Comment