CPSC-I-10-0003
INTERAGENCY AGREEMENT (IAG)

BETWEEN THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION

AND THE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

CDC IAA # 10-07
CPSC IAA # 10-0003

I. INTRODUCTION

The U.S. Consumer Product Safety Commission, hereinafter referred to as CPSC, and the Centers for Disease Control and Prevention, National Institutes for Occupational Safety and Health, hereinafter referred to as NIOSH, hereby agree that NIOSH, subject to the terms and conditions herein, shall perform the necessary research for determining and quantifying the potential health effects of nanoparticles released from aerosol spray products.

II. TITLE

Pulmonary Effects of Titanium Dioxide Nanoparticles Released from Aerosol Spray Products.

III. BACKGROUND

In FY'08 the U.S. Consumer Product Safety Commission (CPSC) initiated an Interagency Agreement with the National Institute for Occupational Safety and Health (NIOSH) to evaluate the particulate aerosol generated during use of an antimicrobial spray product containing TiO_2 nanoparticles. CPSC purchased the spray bathroom cleaner/sanitizer and provided approximately $40,000 to NIOSH for construction of a generation system and test chamber and the characterization of the generated aerosol. NIOSH provided the expertise and staff time to conduct this project.

NIOSH deliverables were:

1) construction of a test chamber to allow generation and characterization of the test aerosol,
2) construction of an automated finger to dispense the aerosol from the spray can,
3) characterization of the generated particulate aerosol (mass, particle size distribution, and chemical composition of the particles)
4) provide a report to CPSC by June, 2009.

Accomplishments:

1) The automated finger has been designed, constructed and tested.
2) The test chamber with observation windows, sampling ports, and an exhaust vent via a HEPA filter has been constructed and tested.
3) The test aerosol has been generated, and the aerosolized particles characterized for mass, particle size distribution, and chemical composition.
4) A preliminary report has been provided to CPSC in December, 2008 and a final report was submitted in June, 2009.

IV. PURPOSE AND OBJECTIVES

Since a particulate aerosol from a bathroom cleaner/sanitizer containing TiO_2 nanoparticles has been successfully generated and characterized, the next step would be to evaluate the acute bioactivity of these particles. This will provide an indication of the potential health effects of these materials on humans who may use or be exposed to the contents of the aerosol spray. The proposed study will expose rats by inhalation to the aerosolized spray particles (low and high dose) for 2 hours and monitor pulmonary responses at 1, 7, and 28 days post-exposure. An analogous study evaluating the pulmonary toxicity of a leather protectant spray product has been conducted previously by our laboratory (Hubbs, et al. Acute lung injury induced by a commercial leather conditioner. Toxicol. Appl. Pharmacol. 143: 37-46, 1997).

V. STATEMENT OF WORK

A system to consistently generate a test aerosol of the bathroom cleaner/sanitizer spray will be constructed. Rats will be exposed to this spray for 2 hours at a high or low dose and pulmonary response at 1 day, 7 days, and 28 days post-exposure will be determined.

A. Aerosol generator:

A computer-controlled solenoid "finger" will be used to periodically press the nozzle-value of the spray can (0.1 second spray every 15 seconds for 2 hours). Exposure concentration (mg/m^3) in the animal exposure chamber will be estimated every 10 seconds using a light scattering monitor (DataRam, Model PDM-3). Mass concentration will be verified by gravimetric analysis of filter samples. Exposure concentration can be changed (high vs. low dose) by adjusting diluent air using a computer-controlled feedback system from the DataRam output of chamber concentration. Such a system has been demonstrated to generate a target aerosol concentration with a variation of less than 15% over a 2 hour exposure period (Hubbs et al. Toxicol Appl. Pharmacol143: 37-46, 1997).

B. Animal exposure:

Specific - pathogen-free, Sprague-Dawley rats (200g) will be divided into the following groups:

1. filtered air controls - 12 rats/time
2. high dose (target 2 mg/m^3) - 12 rats/time
3. low dose (target 1 mg/m^3) – 12 rats/time

Rats will be exposed for 2 hours, and 3 post-exposure times will be evaluated (1 day, 7 days, and 28 days post-exposure). The total number of rats in this study will be 108.

C. **Pulmonary** responses:

1. Breathing pattern can be used to evaluate airway irritation/airway resistance (Castranova et al. Intern. Immuno Pharmacol. 2: 163 - 172, 2002). Breathing pattern (12 rats/group) will be measured in a glass plethymorgraph immediately before and after exposure as well as immediately before sacrifice.

2. Pathological analysis:
   Histopathology (5 rats/group) will be evaluated as described previously (Hubbs et al. Toxicol Appl Pharmacol 143: 37-67, 1997). Briefly, lungs will be excised and perfusion fixed with 10% neutral-buffered formalin or Karnovsky's solution. Lung tissue will be processed, paraffin embedded, and stained with hematoxylin and eosin. Tissue sections will be examined under light microscopy and scored for severity and distribution of inflammation/damage by a board-certified veterinary pathologist. Lung tissue will also be processed and evaluated by electron microscopy. The distribution of TiO_2 particles will be determined by energy dispersive x-ray analysis.

3. Pulmonary inflammation and damage:

   Bronchoalveolar lavage (7 rats/group) will be conducted as previously described (Porter et al. Toxicol. Sciences 79: 370-380,2004). The first a cellular lavage fluid will be evaluated for albumin as an indication of lung damage. Cell number and cell differentials will be determined using an electronic cell counter and microscopic evaluation of cytospin preparations from the lavage samples as an indication of pulmonary inflammation. Chemiluminescence by alveolar macrophage will be monitored using a luminometer as an indication of macrophage activation (Porter et al. Am J. Physiol Lung Cell Mol Physiol 283: L485-L493, 2002).

VI. RESOURCES

NIOSH RESOURCES

NIOSH will provide personnel, laboratory support, laboratory animals, and an inhalation facility necessary to perform tasks described under this agreement. The cost of this contribution is estimated at $142,680.

CPSC RESOURCES

CPSC will provide NIOSH with the bathroom cleaner to be tested. In addition, CPSC will provide funding to NIOSH in the amount of $74,257 for supplies and equipment as described in Section XIII.

VII. NONDISCLOSURE OF DATA

The Contractor agrees that it and its employees will not disclose any data obtained or developed under this contract to third parties without the consent of the U. S. Consumer Product Safety Commission Contracting Officer.

VIII. REPORTING REQUIREMENTS

NIOSH will provide preliminary test reports documenting the test protocols and resulting data at the completion of each task. Within 60 days of completion of the testing, NIOSH will issue a draft final report for CPSC staff review. Following CPSC staff review, NIOSH will have an additional 30 days to deliver the final report summarizing the test data.

DELIVERY ITEM	QUANTITY	PERFORMANCE
A. All recorded test data and findings	2 copies	Within 7 days of completion
B. Representative photographs	2 copies	Within 7 days of completion

IX. PERIOD OF PERFORMANCE

The period of performance shall begin on the effective date and shall not extend beyond December 31, 2010. This agreement may be modified or cancelled by mutual consent of CPSC and NIOSH.

X. DELIVERY OR PERFORMANCE

All deliverables required under the terms and conditions of this IAG shall be provided to the CPSC. The activities planned under this agreement are expressly subject to the availability of funds and other necessary resources to the parties.

NIOSH neither commits nor makes any obligation of funds pursuant to this agreement. The following items shall be performed or delivered in accordance with the following schedule:

The period of performance for this agreement is from the date of signature by both parties through December 31, 2010. Completion Date: A final report will be submitted from NIOSH to CPSC by December 31, 2010.

XI. DISAGREEMENTS

In the event that the CPSC and NIOSH have a disagreement arising under this Interagency Agreement, then the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved between them, then the parties agree to seek the assistance of a third party in resolving the disagreement.

XII. LIASON OFFICERS

a. NIOSH PROJECT OFFICER

Vincent Castranova, Ph.D.
Chief, Pathology and Physiology Research Branch
Health Effects Laboratory Division, NIOSH
1095 Willowdale Road, MS 4020
Morgantown, WV 26505
Phone: 304-285-6032
Fax: 304-285-5938
vic1@cdc.gov

b. CDC/NIOSH FMO BUDGET ANALYST

Sandy Stafford
Budget Analyst
CDC/OD/OCOO/FMO
1095 Willowdale Road, MS 4020
Morgantown, WV 26505
Phone: 304-285-6207
Fax: 304-285-6126

c. *CPSC PROJECT OFFICER*

Treye A. Thomas, Ph.D
U.S. Consumer Product Safety Commission
Office of Hazard Identification and Reduction
4330 East West Highway
Bethesda, MD 20814
Phone: (301) 504-7738
Fax: (301) 504-0779
E-mail: tthomas@cpsc.gov

d. *CPSC FINANCIAL OFFICER*

Ms. Deborah Peebles Hodge
U.S. Consumer Product Safety Commission
4330 East West Highway,
Bethesda, MD 20814
Phone: (301) 504-7130
Fax: (301) 713-1535
E-mail: dhodge@cpsc.gov

XIII. COST AND TRANSFER OF FUNDS

CPSC will provide $74,257 in FY 2010 to support the activities described in this agreement.

Materials and supplies	*Cost*	*Responsible Agency*
Obj Code 31 - Inhalation Equipment	$35,000	CPSC
Obj Code 26 - Pulmonary Response supplies and lab support	$33,126	CPSC
CDC Overhead charge (9%)	$ 6,131	CPSC
Total	***$74,257***	***CPSC***

XIV. FUNDING AND ACCOUNTING DATA

The transfer of funds shall be from CPSC to NIOSH through the On-Line Payment Collection (OPAC) system using the following accounting data:

Transfer From:
CPSC
Taxpayer ID Number (TIN): 520978750
Agency Location Code (ALC): 61000001
DUNS 069287522
US Treasury Code: 61-0100
AMOUNT: $ 74,257.00
0100A10DPS 2010 2370400000 EXHR004000 253A0

To:
NIOSH
Taxpayer ID Number (TIN): 586051157
Agency Location Code (ALC): 75090421
DUNS: 927645465
US Treasury Code: 75-10-0943

XV. AUTHORITIES

FOR CPSC:
Section 27(g) of the Consumer Product Safety Act, (15 U.S.C. 2076(g)),

FOR NIOSH
The Public Health Service Act.

Approved and Accepted for CDC/NIOSH:

BY: _____ 2/26/2010

Kelley Durst
Associate Director for Planning and Performance
National Institute for Occupational Safety and Health
2400 Century Parkway NE (4th Floor)
Atlanta, GA 30345
Phone: (404) 498-2500
Fax: (404) 498-2573

Approved and Accepted for CPSC

BY: _____ 3/18/10

Donna Hutton
Director, Division of Procurement Services
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
Phone: (301) 504-7009
Fax: (301) 504-0628

Public Health Service

Centers for Disease Control and Prevention & Agency for Toxic Substance and Disease Registry

INTER/INTRA-AGENCY AGREEMENT (IAA)

Receivable Agreements (CDC/ATSDR is Performing Work)

1. CDC IAA #:	2. PROCURING AGENCY IAA#	3. TYPE OF AGREEMENT:
10-07	10-0003	☒ New ☐ Modification ☐ Administrative Modification Number:

4. TITLE OF PROJECT:
Pulmonary Effects of Titanium Dioxide Nanoparticles Released from Aerosol Spray Prod

5. Type of Customer
☒ FED ☐ Non-FED ☐ Non-FED Billing

6. DESCRIPTION OF WORK: (*Please attach*)
SEE ATTACHED

AMOUNT: (*Not to exceed without written modification*)
$74,257.00

7. NAME AND ADDRESS OF PROCURING AGENCY:
US Consumer Product Safety Commission
Office of Hazard Identification and Reduction
4330 East West Highway
Bethesda MD 20814 DUNS #069287522

Liaison Name: Treye A. Thomas Phone: (301) 504-7738
Email: tthomas@cpsc.gov Fax: (301) 504-0779

8. NAME AND ADDRESS OF CDC CENTER, INSTITUTE OR OFFICE
NIOSH/HELD
1095 Willowdale Road, MS 4020
Morgantown WV 26505-2888 DUNS #927645465

Liaison/Project Manager: Vincent Castranova Phone: (304) 285-6032
Email: vic1@cdc.gov Fax: (304) 285-5938

9. PROJECT PERIOD:
From: 10/01/2009 Through: 12/31/2010

BUDGET PERIOD:
From: 10/01/2009 Through: ~~09/30/2010~~ 12/31/10

If agreement is longer than **one year**, the following statement applies and must be included in the agreement narrative: "*This agreement is approved for Fiscal Year 2010 and may continue during Fiscal Year 2011, subject to availability of funds.*"

10. AUTHORITY: (CDC)
☐ Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535 and 1536 (*If detail of CDC personnel, justification is required.*)
☒ Other. (*Please specify*) PUBLIC HEALTH SERVICE ACT

11. AUTHORITY (*Procuring Agency*):
Section 27(g) Consumer Prod Safety Act (15 USC 2076(g)

☒ CDC Standard Overhead (9% will be applied to all reimbursable agreements)
☐ CDC Overhead Waiver granted and approved by FMO Branch Chief

12. CDC FUNDING INFORMATION:
Treasury Symbol/Appropriation: 75-10-0943
Budget Activity: 5611-RF-11-01
Owning Org. Admin. Code: CCCC
Fund Value: 921 60 2010 1RAO
Crosscutting Code: 28111

CDC ALC 75090421
CDC EIN 586051157

FISCAL YEAR: 2010

CAN #1:	Direct Costs:	$ 68,126.00	
CAN #2:	CIO Indirect:	$	%
CAN #3:	CDC Indirect:	$ 6,131.00	9 %
	Total:	$ 74,257.00	

13. PROCURING AGENCY BILLING REQUIREMENTS:
Treasury Symbol/Appropriation: ~~[illegible]~~ 61-0100
ALC: 61000001
EIN: 520978750
DUNS #: 069287522

Billing will be processed through the use of the Intra-Governmental Payment and Collection (IPAC) system.
Billing Frequency: ☐ Monthly ☒ Quarterly
☐ Other:

14. ADDITIONAL BILLING REQUIREMENTS OF THE PROCURING AGENCY: (*Required if needed for invoice payment.*)
N/A

15. PROCURING AGENCY BUDGET CONTACT:
Name: Deborah Peebles Hodge Phone: (301) 504-7130
Email: dhodge@cpsc.gov Fax:

CIO CONTACT:
Name: Joyce A. Blosser Phone: (304) 285-6125

CDC FMO BUDGET CONTACT:
Name: Sandra Stafford Phone: (304) 285-6207

16. OTHER REQUIREMENTS
A. Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.
B. Unless otherwise requested by the procuring agency, CDC will retain title to any equipment procured in order to provide service.

17. CDC ACCEPTANCE: (*Please print*)
Name: Kelley Durst
Title: Associate Director for Planning & Performance/NIOSH
Email Address: KDurst@CDC.GOV
Signature: [signature] Date: 2/10/10

18. PROCURING AGENCY ACCEPTANCE: (*Please print*)
Name: Donna Hutton
Title: Director, Division of Procurement Services/CPSC
Email Address: DHutton@CPSC.GOV
Signature: [signature] Date: 3/18/10

This agreement may be terminated by either agency upon a 30 day advance written notice. This agreement may be modified by mutual written consent of all parties.

FORM WITH THE ORIGINAL OF THE INTERAGENCY AGREEMENT THROUGH APPROPRIATE CHANNELS.

1. TO: *Assoc Dir for Management and Operations, NIOSH*

2. FROM: Executive Office, NIOSH

3. INTERAGENCY AGREEMENT TITLE:

Pulmonary Effects of Titanium Dioxide Nanoparticles Released from Aerosol Spray Products

4. NAME OF AGENCY AS IN AGREEMENT:
U.S. Consumer Product Safety Commission

5. DATE INITIATED: 02-02-2010

7. ACCOUNTING DATA: ACCOUNTING POINT 21/27
APPROPRIATION 75-10-0943

ALLOWANCE 11B18 CAN see attached

COST CENTER attached OBJ CLASS attached

TRANSFER OF FUNDS&AMOUNT $
NIOSH to Agency x Agency to NIOSH
☐NO FUNDS TRANSFERRED

SOURCE OF FUNDS:
☐Base Funds
x Reimbursable Funds
Direct $68,126
Indirect $ 6,131
Total $74,257

8. NIOSH PROJECT OFFICER	9. BRANCH, DIVISION	10. TELEPHONE NUMBER
Vincent Castranova (PI)	PPRB/HELD	304-285-6032
11. AGENCY PROJECT OFFICER	**12. ADDRESS**	**13. TELEPHONE NUMBER**
Treye A. Thomas	4330 East West Highway Bethesda, MD 20814	301-504-7738

14. TYPE OF AGREEMENT:
XXX New _____ ☐Modification of 6012 # _____ ☐ Modification of Agreement No. _____

15. CLEARANCE REQUIRED:
xNone ☐Federal Report Act (OMB) ☐Conference
☐Human Subjects ☐Peer Review ☐Other _____
☐Computer ☐Tripartite Review

17. FIELD APPROVALS&SIGNATURE AND TITLE

A. PROJECT OFFICER — A. DATE
Vincent Castranova — 2/3/10

B. BRANCH CHIEF — B. DATE
2/3/10

C. DIVISION/OFFICE DIRECTOR — C. DATE
Albert E Munson — 2/4/10

18. INSTITUTE APPROVAL- SIGNATURE AND TITLE

Associate Director for Planning & Performance, NIOSH

2/10/10
Date

16. NAME, ADDRESS, PHONE, AND FAX NUMBER OF PERSON AT OTHER AGENCY WHO SHOULD RECEIVE THE INTERAGENCY AGREEMENT APPROVAL PACKAGE.

Ms. Deborah Peebles Hodge
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
Phone: (301) 504-7130
Fax: (301) 713-1535
E-mail: dhodge@cpsc.gov

19. FINANCIAL MANAGEMENT APPROVAL- SIGNATURE AND TITLE

Sandra Stafford
BUDGET ANALYST, FINANCIAL MANAGEMENT OFFICE, CDC

2/9/2010
DATE

20. DISTRIBUTION:
FMO CINCINNATI - ACCOUNTING POINT 27 ONLY
FMO ATLANTA - ACCOUNTING POINT 21 ONLY
ATLANTA BUDGET OFFICE
BUDGET ANALYST, FMO

21. KEY DATES LEAVE BLANK)	REC=D in ATL Budget Office	CLEARANCES OBTAINED	NIOSH APPROVAL	TO AGENCY	AGENCY APPROVAL	EXPIRATION DATE

C/NIOSH REV 05/2003