CPSC-I-12-0012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INTERAGENCY AGREEMENT

1. IAG NO. (FDA)	2. TYPE OF AGREEMENT	3. MODIFICATION NO.
224-12-8029	☒ New ☐ Mod ☐ Administrative ☐ No Cost Ext.	

4. TITLE OF PROJECT
Consumer Products Saftey Commission (CPSC) and FDA

5. SECURITY CLAUSE APPLIES
☐ Yes (See attached) ☒ No

DESCRIPTION OF WORK - ATTACHED
See attached .

7. AMOUNT
$100,000.00

8. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY
Leader, Chemical Hazards Program
Office of Hazard Identification and Reduction
U.S. Consumer Product Safety Commission
4330 East West Highway Suite 600
Bethesda, MD 20814

9. LIAISON TO PARTICIPATING FEDERAL AGENCY
a. Name: Treye A Thomas, Ph.D
b. Phone No.: (301) 504 - 7738
c. E mail: tthomas@cpsc.gov
d. FAX No.: (301) 504 - 0079

10. NAME AND ADDRESS OF PARTICIPATING FDA UNIT
Food and Drug Administration/Emerging Technology Programs
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue, WO32-4264
Silver Spring, MD 20993-0002

11. LIAISON TO PARTICIPATING FDA UNIT
a. Name: Carlos Peña, PhD, MS
b. Phone No.: (301) 796 - 8521
c. E mail: carlos.pena@fda.hhs.gov
d. FAX No.: (301) 847 - 8617

12. PERIOD OF AGREEMENT
FROM: June 1, 2012 THROUGH: November 30, 2013

This agreement may be terminated by either party upon a thirty day advance written notice. If this Agreement is funded by the FDA, FDA will retain title for any equipment procured under this agreement, unless otherwise justified in the statement of work.

13. AUTHORITY (FDA)
☒ Economy Act approved June 30, 1932, as amended by 31 U.S.C. 1535
☐ Section 301 of the Public Health Service Act (42 USC 241)
☐ Other *(specify)* _____

14. AUTHORITY *(Other Agency)*
GETA (5 USC 41), OPM Revolving fund Authority (5 USC 1304) and E.O. 11348

15. FDA FUNDING INFORMATION
☒ Increase from $ _____ by $ 100,000.00 to $ 100,000.00
☐ Decrease from $ _____ by $ _____ to $ 0.00

From CPSC - TIN:520978750;DUNS 069287522,ALC 61-00-0001,$100,000 To FDA-TIN 53-0196965; ALC 75-06-0099, DUNS 927645523,Tresury CODE 75120600CAN # 6999AJY, $100,000
TAG: 12xxxxxxxxNANO

16. Administrative billing requirements will comply with GAO Policy and Procedures, Title 7, Section 8.4

☐ Billing: _____ IPAC system FDA ALC 75060099 Other Agency ALC _____

☐ _____ SF 1080 - FDA Accounting (HFA-120) 5600 Fishers Lane, Rockville, MD 20857

17. PARTICIPATING AGENCY FUNDING INFORMATION *(This block must be completed if funding is being provided to the FDA.)*
Note: a. Legal authority for the acquisition of supplies/services exists within your agency.
b. This action does not conflict with any other agency's authority or responsibility.

18. PARTICIPATING AGENCY IS
☒ Required to sign ☐ Not required to sign

19. FDA ACCEPTANCE

20. PARTICIPATING AGENCY ACCEPTANCE 6/29/12

FDA 3443 (1/02)

Created by: PSC Media Arts Branch (301) 443-2454 EF

NAME: Kimberly Pendleton Chew	NAME: Donna Hutton
TITLE: Team Leader DASG/GAAT/OAGS/FDA	TITLE: Contracting Officer
DATE: 6/28/2012	DATE: Donna Hutton 6/29/12

INSTRUCTIONS

1. Complete this form to establish or renew an Interagency Agreement with the Food and Drug Administration.
2. Once an Interagency Agreement number has been established, all correspondence must bear that number.
3. For additional assistance, please call the Division of Contracts & Procurement Managment, OFACS (301) 827-7150.

CPSC-I-12-0012

INTERAGENCY AGREEMENT (IAG)
BETWEEN THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION
AND THE
U.S. FOOD AND DRUG ADMINISTRATION

I. INTRODUCTION

This document describes an agreement between the U.S. Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC) to jointly investigate certain commercially available consumer products (e.g., cookware, kitchen utensils, and food storage containers) that come into contact with food and that may contain nanomaterials. The overarching goal of this agreement is to establish standard operating procedures and guidelines for evaluating CPSC and FDA-regulated products that involve the application of nanotechnology.

II. TITLE

Joint CPSC and FDA NANOtechnology Regulatory Science Research Food Contact Products Containing Nanomaterials Study (Short Title- CPSC FDA NANO).

III.BACKGROUND

Nanotechnology, which involves the science of manipulating materials at an atomic or molecular scale, could have a broad range of applications, including in consumer products that come into contact with food. Both CPSC and FDA regulate a wide range of consumer products that may contain nanomaterials, including products that come into contact with food. As explained in the memorandum of understanding (MOU 225-76-2003) between CPSC and FDA, products having food contact surfaces (such as food containers, and food cooking, eating, and preparation articles) from which there is migration of a substance from the contact surface to the food, are subject to regulation by FDA. CPSC has regulatory authority over these products for hazards unrelated to migration. This agreement provides for CPSC and FDA to cooperate and ensure

consistency, when possible, regarding the approaches to identifying and addressing potential safety hazards involving products containing nanomaterials.

This agreement also supports the responsible development of nanotechnology, a strategic goal of the United States, under the National Nanotechnology Initiative [NNI] Strategic Plan, accessible online at http://www.nano.gov/sites/default/files/pub_resource/2011_strategic_plan.pdf. The National Nanotechnology Initiative is intended to help coordinate Federal nanotechnology research and development, including coordinating the multiagency efforts in nanoscale science, engineering, and technology. Discussions between CPSC and FDA under the NNI, and in subsequent meetings between both agencies, helped to establish this joint investigation.

CPSC Statement

The U.S. Consumer Product Safety Commission is an independent regulatory agency created in 1973. CPSC's jurisdiction includes thousands of types of consumer products used in or around the home. The introduction of consumer products containing nanomaterials into the marketplace may require unique exposure and risk assessment strategies. One of the primary data needs will be the identification of the specific nanomaterial in the consumer product. Identifying any potential health hazards from a specific product will require characterization of the nanomaterials to which a consumer is exposed during product use, including assessment of the size distribution of the materials released. Once the exposure has been characterized, toxicological data that is appropriate for the particle sizes represented in the exposure assessment will be used in any assessment of health risks.

FDA Statement

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, our nation's food supply, cosmetics, dietary supplements, and products that give off radiation. FDA is also

responsible for advancing the public health by helping to speed innovations and helping the public get the accurate, science-based information they need in order to use medicines and foods to improve their health.

The overarching goal and specific objectives of this IAG link to FDA's Nanotechnology Regulatory Science Plan to foster the responsible development of FDA-regulated products that may contain nanomaterials or otherwise involve the application of nanotechnology (FDA's Nanotechnology Regulatory Research Plan is accessible online at http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm273325.htm).

IV. PURPOSE AND OB JECTIVES

The purpose of this research is to jointly investigate certain commercially available consumer products (e.g., cookware, kitchen utensils, and food storage containers) that come into contact with food and that may contain nanomaterials. The research will assess whether the current methods for determining migration of conventional additives from consumer products are applicable to the evaluation of nanomaterials used in consumer products that contact food. The objective is to also establish standard operating procedures and guidelines for evaluating consumer products that come into contact with food and that may involve the use of nanomaterials.

Scientific Knowledge to be Achieved

The CPSC FDA NANO Study targets the following categories of knowledge which are necessary to support decision-making in consumer products that come into contact with food:

- Identification of nanomaterials currently used in commercially available products that come into contact with food.
- Identification of methods for the "in-product" and "in-use" characterization of nanomaterials.

- Enhanced understanding of the potential migration of nanomaterials from commercially available products that come into contact with food; and the applicability of established migration models and testing conditions to such products containing nanomaterials.
- Quantitative assessment of potential consumer exposures.

Public Health Impact

The application of nanotechnology may result in product attributes that differ from those of conventionally-manufactured products, and thus may merit examination. The CPSC FDA NANO Study is intended to provide integrated knowledge about current applications of nanotechnology in consumer products that come into contact with food, to better monitor products that may use nanomaterials, and to further understand and predict their safe use.

V. STATEMENT OF WORK

The aim of the JOINT CPSC FDA NANO Study is to:

- Identify commercially available consumer products that come into contact with food (e.g., cookware, kitchen utensils, and food storage containers), which may contain nanomaterials.
- Quantify the physical and chemical characteristics of nanomaterial(s) used in such products and quantify the likelihood of nanomaterial migration and subsequent consumer exposure.
- Establish standard operating procedures and guidelines for evaluating consumer products that come into contact with food and that involve the use of nanomaterials.

FDA Investigators will:

- Identify commercially-available consumer products that come into contact with food (e.g., cookware, kitchen utensils, and food storage containers) which may contain nanomaterials.

- Measure physical and chemical characteristics of the identified products, including characterization of the bulk material and nanomaterial.
- Identify potential consumer exposure pathways and evaluate, under intended use conditions, the release/migration of nanomaterials from the commercial products.
- Evaluate the applicability of current migration models and testing conditions to the evaluation of products containing nanomaterials.
- Based on the products identified, and the characterization and migration data, identify possible gaps in toxicological research, and recommend additional studies, as needed.

Proposed outcomes of this IAG will include information applicable to CPSC, FDA, other Federal agencies, and the broader environmental, health, and safety (EHS) community such as:

- Scientifically-credible standard operating procedures and guidelines for evaluating consumer products that come into contact with food and that may contain nanomaterials.
- Potential migration pathways and exposure analyses for such products.

VI. FDA BUDGET, FURNISHED MATERIALS/EQUIPMENT, & STAFFING

Budget

Funding for this study will be provided by CPSC to FDA under this IAG, in the amount of $100,000. FDA will also contribute $100,000 to this project. The total cost of the JOINT CPSC FDA NANO study is $200,000.

Furnished Materials/Equipment

The FDA agrees to furnish all equipment, materials, services, and facilities to complete the objectives listed in Section V. Unless otherwise requested by the CPSC and the FDA, the FDA will retain title to any equipment procured in order to provide service for this project.

Staffing

The CPSC and the FDA agree to engage all necessary personnel on the CPSC FDA NANO Study. Staff Travel under this agreement is subject to allowances authorized in accordance with Federal Travel Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

VII. NONDISCLOSURE OF DATA

The CPSC and the FDA agree that it and its employees will not disclose any data obtained under the CPSC FDA NANO Study or developed under this IAG to third parties without the consent of the CPSC and FDA.

VIII. REPORTING REQUIREMENTS

The FDA will draft preliminary reports documenting the methods, protocols, resulting data, etc., at the completion of each task. Within 60 days of completion of each performance goal, the FDA will issue a draft final report for CPSC review. Following the CPSC review, FDA will develop one final report summarizing the data within 30 days.

IX. PERIOD OF PERFORMANCE

The period of performance shall begin on the effective date and shall not extend beyond 18 months from the effective date. This agreement may be modified or cancelled by mutual consent of the CPSC and the FDA.

X. DELIVERY OF PERFORMANCE

All deliverables required under the terms and conditions of this IAG shall be provided to the CPSC and the FDA. The activities planned under this agreement are expressly subject to the availability of funds and other necessary resources to the parties. The following items shall be performed or delivered in accordance with the following schedule:

- Month 3: Identify and procure commercially-available consumer products that come into contact with food and that may contain nanomaterials.

- Month 9: Characterize these products, identifying if they contain nanomaterials and the composition and physical characteristics of the nanomaterials. Characterize the bulk properties of the products, such as polymer identification and density, additional additives, etc.

- Month 12: Determine potential exposure routes and evaluate migration of the nanomaterials using established protocols. If necessary, begin generating in-house test samples to be used in the evaluation of migration protocols. Evaluate results within the context of current characterization data and implications for development of further characterization, migration, and toxicological research, as appropriate.

- Month 18: Report on nanomaterial characterization and migration results from the identified commercial products and in-house test samples. Develop standard operating procedures (SOPs) for migration testing and "in-product" nanomaterial characterization. Develop outlines/drafts of SOPs for migration testing. Provide recommendations about characterization, migration, and toxicological testing based on "in-product" and post-use, as appropriate.

The period of performance for this agreement is 18 months from the date of signature by both parties.

XI. DISAGREEMENTS

In the event that the CPSC and the FDA have a disagreement arising under this IAG, the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved, then the parties agree to seek the assistance of a third party to resolve the disagreement.

XII. LIASON OFFICERS

1. CPSC Liaison Officer

   Treye A. Thomas, Ph.D.
   Leader, Chemical Hazards Program
   Office of Hazard Identification and Reduction
   U.S. Consumer Product Safety Commission
   4330 East West Highway Suite 600
   Bethesda, MD 20814
   Tel 301-504-7738
   Fax 301-504-0079
   Email tthomas@cpsc.gov

2. FDA Liaison Officers

   Gregory O. Noonan, Ph.D.
   Deputy Director (Acting), Office of Food Additive Safety
   Food and Drug Administration
   5100 Paint Branch Parkway
   College Park, MD 20740

   Tel 240-402-2250
   Fax 301-436-2634
   Email gregory.noonan@fda.hhs.gov

   Carlos Peña, PhD, MS
   Director
   Emerging Technology Programs
   Office of the Commissioner
   Food and Drug Administration

10903 New Hampshire Avenue
WO32-4264
Silver Spring, MD 20993-0002
Tel 301-796-8521
Fax 301-847-8617
Email carlos.pena@fda.hhs.gov

XIII. PAYMENT OFFICE INFORMATION

1. CPSC PAYMENT OFFICE
   CPSC Accounts Payable Branch, AMZ-160
   PO Box 25710
   Oklahoma City, OK 73125

   AGENCY PAYMENT OFFICER:
   Debbie Young, Agency Payment Officer
   Enterprise Service Center
   Office of Financial Operations
   Federal Aviation Administration
   PO Box 25710
   Oklahoma City, OK 73125
   (405) 954-7467
   9-AMC-AMZ-CPSC-Accounts-Payable@faa.gov

XIV. COST AND TRANSFER OF FUNDS

The total estimated cost for the initial phase of this IAG is estimated at $100,000, provided with CPSC FY- 2012 funds.

FDA Administrative Point of Contact:
Carrie Bryant

Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel 301-796-8215
Fax 301-847-8616
Email carrie.bryant@fda.hhs.gov

XV. ACCOUNTING DATA

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

Transfer From:
CPSC
BETC: DISB
Taxpayer ID Number (TIN): 520978750
Agency Location Code (ALC): 61-00-0001
DUNS 069287522
US Treasury Code: 61120100
AMOUNT: $ 100,000.00
ACCOUNTING DATA: 0100A12DPS 2012 2370400000 EXHR004000 255AO

To:
BETC: COLL
Taxpayer ID Number (TIN): 53-0196965
Agency Location Code (ALC): 75-06-0099
DUNS 927645523
US Treasury Code: 75110600
AMOUNT: $ 100,000.00
ACCOUNTING DATA: CAN 6999AJY

Approved and Accepted for
Food and Drug Administration

BY: _____

Kimberly Pendleton Chew

TITLE: Team Leader DASG/GAAT
Office of Acquisitions and Grants Services

DATE: 6/28/2012

Approved and Accepted for
Consumer Product Safety Commission

BY: _____

Donna Hutton

TITLE: Contracting Officer

DATE: 6/29/12