



INTERAGENCY AGREEMENT

CPSC-IAG-03-1311

1. IAG NO. (FDA) 224-03-2781		2. TYPE OF AGREEMENT <input checked="" type="checkbox"/> New <input type="checkbox"/> Mod <input type="checkbox"/> Administrative		3. MODIFICATION NO.	
4. TITLE OF PROJECT: A Pilot Collaborative Effort Between the Consumer Product Safety Commission and CPFSAN's Adverse Event Reporting System to Improve Patient Safety					
5. DESCRIPTION OF WORK - ATTACHED			6. AMOUNT \$97,000.00		
7. NAME AND ADDRESS OF PARTICIPATING FEDERAL AGENCY Div. of Hazard & Injury Data Systems, Epidemiology, CPSC 4330 East-West Highway (Room 604H) Bethesda, Maryland 20814			LIAISON NAME: Drucie Besley		PHONE NO. (301) 504-7442
8. NAME AND ADDRESS OF PARTICIPATING FDA UNIT CPFSAN Adverse Event Report System, OSAS 5100 Paint Branch Parkway College Park, Maryland 20740			LIAISON NAME: Debra Rogan		PHONE NO. (301) 436-2586
9. PERIOD OF AGREEMENT			FROM: 08-01-2003		THROUGH: 09-30-2003

This agreement may be terminated by either party upon a thirty day advance written notice

10. 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):

11. AUTHORITY (Other Agency)

12. FDA FUNDING INFORMATION
 Increase from -0- by \$97,000 to \$97,000
 Decrease from _____ by _____ to _____

Approp: 7530600
 CAN: 3-6991948-F-58505
 Obj. Class: 25.38
 PMS Codes: 22390D/40
 DUNS: 927645523

Administrative billing requirements will comply with GAO Policy and Procedures, Title 7, Section 3.4

Billing: _____ OPAC system FDA ALC 75060099 Other Agency ALC 61-00-0001
 _____ SF 1080 - FDA (HFA-120) 5600 Fishers Lane, Rockville, MD 20857

13. PARTICIPATING AGENCY FUNDING INFORMATION
CPSC ACCOUNTING DATA: 03 PS EXOB 4310 11179 253e

- 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.

14. PARTICIPATING AGENCY IS
 Required to sign
 Not required to sign

15. FDA ACCEPTANCE		16. PARTICIPATING AGENCY ACCEPTANCE	
SIGNED: <u>Rosemary T. Springer</u>		SIGNED: <u>Donna Hutton</u>	
NAME: <u>Rosemary T. Springer</u>		NAME: <u>Donna Hutton</u>	
TITLE: <u>Grants Management Officer</u>		TITLE: <u>Contracting Officer</u>	
DATE: <u>8/1/03</u>		DATE: <u>7/30/03</u>	

IAG Number: 224-03-2781

Title: A Pilot Collaborative Effort between the Consumer Product Safety Commission and CFSAN's Adverse Event Reporting System to improve Patient Safety

Background:

The National Electronic Injury Surveillance System (NEISS), maintained and operated by the US Consumer Product Safety Commission (CPSC), is an ongoing surveillance system routinely used to monitor consumer product-related injuries treated in US hospital emergency departments. There are currently 98 NEISS hospital emergency departments that represent a probability sample of all US and US territory hospitals that have at least six beds and provide 24-hour emergency services.¹ Coders review every emergency department record of the 98 hospitals and extract data pertaining to current needs of the NEISS system within three to four days. This system is unique in that it captures emergency room visits, thus potentially the serious or most serious adverse event cases.

The Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (FDA) receives adverse event reports regarding their regulated or monitored products from consumers and health care practitioners. Unfortunately, it is estimated that FDA only receives one percent of the real number of adverse events that occur in the US. Of greatest concern are serious adverse events that may require medical intervention.

Description of Work:

The purpose of this effort is to improve and enhance passive surveillance data capture of adverse events pertaining to CFSAN regulated products. CPSC will use its existing database and surveillance capabilities for this effort.

The goals for the pilot include, but are not limited to:

- Determine compatibility of electronic data capture systems (NEISS and CFSAN's Adverse Event Reporting System (CAERS))
- Capture real time data
- Capture serious adverse events that may routinely escape reporting in CFSAN's CAERS system
- Determine the usefulness of NEISS data to CFSAN's Adverse Event System
- Determine the possibility of increasing the amount of adverse event data for CFSAN through collaboration with CPSC
- Potentially enhance post-marketing surveillance of CFSAN products

- Determine the ability to improve signal detection
- Explore data sets and surveillance tools that already exist in order that FDA not duplicate efforts

CPSC will:

- Work with CSFAN to develop reporting requirements and training materials that provide coders guidance on cases to be collected under this agreement
- Train coders to recognize and capture food, cosmetic, and selected food ingredients (monosodium glutamate (MSG), sulfites or olestra) that may have caused illnesses or injuries found in emergency rooms in NEISS hospitals
- Perform data capture using these materials and reporting requirements in 34 of its 98 hospital emergency rooms for a two-month period
- Collect responses on approximately 15 variables including a "narrative" section on cases reported during this period
- Visit three hospitals, of the 34 (randomly chosen), to perform on-site training and to perform quality control, evaluating data capture by coders
- Initialize their database in order to perform electronic data transfer of the above mentioned fields and narrative section
- Provide daily downloads of data gathered from the 34 emergency rooms over a two-month period, 01 August 2003 through 30 September 2003
- Provide redacted charts from cooperating hospitals of the patients with illness or injuries due to food, cosmetic or selected food ingredients
- Provide more information on approximately nine cases, if needed, by CFSAN

CFSAN, FDA will:

- Work with CPSC to develop reporting requirements and training materials that provide coders guidance on cases to be collected under this agreement
- Determine needs for and perform the mapping needed for electronic transfer of data, to include approximately 15 fields and a narrative
- Develop the ability to receive daily downloads of these cases over a two-month period, 01 August 2003 - 30 September 2003

- Review the data received to determine ability of CFSAN to use this information
- Request more information on approximately nine cases, if needed

Estimated Cost:

CFSAN, FDA will provide CPSC \$97,000 in FY 2003 to perform and use its existing database to enhance adverse event capture of CFSAN regulated products, to include those listed above.

Period of Agreement:

From fully executed agreement to 30 September 2003

Travel:

Travel under this agreement is subject to allowances authorized in accordance with Federal Regulations, Joint Federal Travel Regulations, and/or Foreign Service Regulations.

¹ Kessler E, Reiff L, Schroeder T: *National Electronic Injury Surveillance System (NEISS) Sample Design and Implementation*. Washington, DC: US Consumer Product Safety Commission, 1997.