CPSC-I-98-1145/FDA-224-96-2495
Mod 4

INTERAGENCY AGREEMENT Number **CPSC-I-98-1145**
BETWEEN
THE UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION
AND THE
FOOD AND DRUG ADMINISTRATION;
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

I. Introduction:

The U.S. Consumer Product Safety Commission, hereinafter referred to as CPSC, and the Food and Drug Administration, Center for Food Safety and Applied Nutrition, hereinafter referred to as FDA/CFSAN, hereby agree that FDA/CFSAN shall provide bioassay testing of product samples and subsequent test results to CPSC and that CPSC will allow FDA/CFSAN to use the test results and remaining bioassay products for its *in vitro* work, in accordance with the terms and conditions set forth below.

II. Title:

Ocular Irritation Testing, Dermal Irritation Testing, Oral Toxicity Testing

III. Purpose:

To establish an Interagency Agreement (IAG) between the Food and Drug Administration (FDA/CFSAN) and the United States Consumer Product Safety Commission (CPSC) for FDA/CFSAN to provide bioassay testing and subsequent results to CPSC and for CPSC to share the testing data and remaining bioassay products with FDA/CFSAN for its *in vitro* work.

IV. Background:

CPSC administers the Federal Hazardous Substances Act, which requires determination of hazards posed by products. As part of its compliance program, CPSC previously conducted bioassay testing in-house to determine the hazard certain regulated products pose to the public as well as to determine appropriate cautionary labeling for these products. CPSC no longer has the facilities or staff to maintain animal facilities nor to perform bioassay testing in-house.

FDA staff developed the original skin and eye irritancy testing procedures known as the Draize tests. FDA continues to maintain its expertise in acute toxicity testing including the eye and skin irritation testing and alternatives to such testing. FDA

through previous IAG's, has provided bioassay testing to the CPSC and received use of the test data and remaining bioassay products for use in its own *in vitro* work.

By establishing this IAG, FDA/CFSAN will provide the bioasssay testing and results to CPSC in support of the compliance program, thereby serving the mission of the Commission to reduce the risk of injury and death to the public. Likewise, CPSC will continue to allow FDA/CFSAN the use of the testing data and remaining bioassay products, necessary for its *in vitro* work.

V. Description of Work:

A. CPSC will provide:

1. All sample products for use in tests.

2. A written description of the testing to be performed with each product sample.

3. A memorandum that details why currently available data is not sufficient for CPSC to reach a conclusion about the potential hazard(s) posed by the product.

B. FDA/CFSAN shall provide:

1. All testing of products provided by CPSC.

2. All personnel, facilities, supplies, materials, and animals, to be used in the tests, with the exception of the product samples to be tested. FDA/CFSAN shall also provide for the care and housing of the animals.

3. Up to 15 tests (eye, skin or oral toxicity) at the FDA's MOD I facility, using the following procedures within the existing protocols approved by the FDA/CFSAN Animal Care and Use Committee. Depending on what the sample is, it may be considered for skin, eye, and oral toxicity testing as described below.

a. Skin Tests

(1) Skin irritation testing will be conducted prior to any eye irritation testing. If the product is determined to be a primary skin irritant (PII $\geq$ 5.0), then it is also considered an eye irritant and no eye test shall be performed. If the product is determined to not be a primary skin irritant (PII $\leq$

4.9), then an eye test shall be performed.

(2) For the skin test, the product will be applied to rabbits for a period of 4 hours. At the end of the exposure time, the product will be removed and the responses graded at 4.5, 24, 48, 72 hours from product application.

b. Eye Tests

(1) Eye irritation tests will be conducted on rabbits and responses graded at 24, 48, 72 hours, and if necessary, 7 days.

c. Oral Toxicity Tests

(1) Toxicity tests will be conducted using rats. The rats will be given a dose of 5000 mg/kg. If necessary, a second test will be done using 50 mg/kg.

4. Provide written results of tests to CPSC Project Officer (see Section VII.) within 5 weeks after receipt of samples. FDA will retain a copy of the results for use in its in-vitro work.

5. FDA/CFSAN may retain a portion of the bioassay test sample for use in its in-vitro work.

6. FDA/CFSAN shall return to CPSC any remaining product sample(s).

VI. Disclosure of Information:

a. The FDA/CFSAN shall submit to the Commission any report, manuscript or other document containing the results of work performed under this Agreement, before such document is published or otherwise disclosed to the public, to assure compliance with Section 6(b) of the Consumer Product Safety Act (15 U.S.C. Section 2055(b)), Commission regulations (16 C.F.R. Part 1101), and a Commission directive (Order 1450.2). These provisions restrict disclosure by the Commission or its agents of information that (1) permits the public to identify particular consumer products or (2) reflects on the safety of a class of consumer products. Prior submission allows the Commission staff to review the information and comply with the applicable restrictions. CPSC should be advised of the FDA/CFSAN's desire to submit or publish an abstract or a report as soon as practical.

b. Any publications of or publicity pertaining to, the work performed under this Agreement shall include the following:

"This project includes or is based on data that was acquired with funds from the Consumer Product Safety Commission. The content of this publication does not necessarily reflect the views of the Commission, nor does mention of trade names, commercial products, or organizations imply endorsement by the Commission.

VII. CPSC Project Officer:

Consumer Product Safety Commission
Directorate for Epidemiology and
Health Sciences
Division of Health Science
Room 522
Washington, D.C. 20207

Dr. Kailash Gupta

Telephone: (301)504-0994 ext. 1386

VIII. CPSC Financial Officer:

Consumer Product Safety Commission
Directorate for Administration
Accounting Operations
Room 522
Washington, D.C. 20207

Ms. Cecelia R. Smith
Agency Payment Officer

Telephone: (301)504-0018 ext. 1137

IX. FDA Project Manager:

Center for Food Safety and Applied Nutrition
Office of Cosmetics and Colors
Cosmetics Toxicology Branch
200 C St. S.W.
Washington, DC 20204

Project Manager: Donnie K. Lowther
Telephone: (202)205-4391

X. Period of Agreement:

This agreement, when accepted by both parties, will have an effective period from date of signature through September 30, 1998, and may be modified by mutual consent of both parties or terminated by either party upon a thirty (30) day advance written notice to the other.

XI. Disagreements

In the event that CPSC and FDA/CFSAN have a disagreement arising under this interagency agreement, the parties shall cooperatively seek to resolve the disagreement by themselves. If the disagreement cannot be resolved between them, the parties agree to seek the assistance of a third party in resolving the disagreement.

XII. Funding:

a. Estimated Cost of Testing

The estimated cost for each test is $600.00. CPSC estimates that a not to exceed maximum of 15 tests may be required to be performed, with a total cost not to exceed $9,000.00. Funding in the amount of $9,000.00 is being provided at this time.

b. Billing

FDA/CFSAN shall provide a quarterly billing for the cost of tests performed during the preceding quarter to the CPSC Agency Payment Officer(see Section VIII). It is mutually agreed that these billings shall represent the actual costs of the articles and services provided, although it may not be possible to itemize and account for individual articles and services.

XIII. Funding and Accounting Data:

The transfer of funds should be through the On-Line Payment and Collection (OPAC) system using the following accounting data:

TRANSFER TO:

FDA/CFSAN Accounting and Appropriation Data:

Appropriation:	7580600
CAN:	8-6991697-X-24801-24812
PMS:	223150/10
Object Class:	25.38

Period of Agreement: 10/1/97 thru 9/30/98

Agency Location number: 75060099

TRANSFER FROM:

CPSC Accounting and Appropriation Data:

98 2 592 33740 25.26 $9,000.00

XIV. Basis for Estimated Costs:

	OBJECT CLASS	
Animals:		26.55
Rabbits	$ 4,950.00	
Rats	$ 2,070.00	
Supplies	$ 98.00	26.51
G&A (11%)	$ 892.00	12.11
Animal Care	$ 990.00*	25.55

* Monies will go directly into contract number: 223-95-2282

XV. Authority:

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

XVI. FASA Compliance:

As the servicing agency, FDA agrees to act in full compliance with Section 1074 of the Federal Acquisition Streamlining Act (FASA) of 1994 entitled ECONOMY ACT PURCHASES.

APPROVED AND ACCEPTED FOR THE UNITED STATES CONSUMER PRODUCT COMMISSION

BY: [signature]

ROBERT J. FROST
CONTRACTING OFFICER

TITLE: CONTRACTING OFFICER

DATE: 7/23/98

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY: Rosemary Springer

Rosemary Springer

TITLE: Senior Grants Management Specialist, OFACS

DATE: 7/23/98