Nutritional Supplements'' workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by encouraging informed dialogue on the future direction of FDA regulation in the context of its historical accomplishments.

The workshop will also help to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which include working more closely with stakeholders and providing access to scientific and technical expertise. Finally, the workshop furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: April 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–4185 Filed 5–1–06; 10:37 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–06–8400]

Memorandum of Understanding Between the Food and Drug Administration, United States Department of Health and Human Services, the Animal and Plant Health Inspection Service, the United States Department of Agriculture, and The National Institutes of Health, United States Department of Health and Human Services Concerning Laboratory Animal Welfare

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The purpose of this Memorandum of Understanding (MOU) is to set forth an agreement between the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, and the National Institutes of Health, U.S. Department of Health and Human Services concerning Laboratory Animal Welfare and FDA (collectively ''the Parties'', or individually as a ''Party'') regarding the framework for reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. This MOU replaces 225–83–8400.

DATES: The agreement became effective February 14, 2006.

FOR FURTHER INFORMATION CONTACT:

For FDA: Rodney T. Allnut, Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, HFC–230, rm. 126, 15800 Crabbs Branch, Rockville, MD 20855, 240–632–6848, FAX: 240–632–6861.

For USDA: Chester Gipson, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, 4700 River Rd., Unit 97, rm. 6A–16, Riverdale, MD 20737–1234, 301–734–4980, FAX: 301–734–4993.

For NIH: Carol Wigglesworth, Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health, Rockwall I, suite 1050, MSC 7982, 6705 Rockledge Dr., Bethesda, MD 20892–7982, 301–496–7163, FAX: 301–402–2803.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: April 26, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING AMONG THE ANIMAL AND PLANT HEALTH INSPECTION SERVICE U.S. DEPARTMENT OF AGRICULTURE AND THE FOOD AND DRUG ADMINISTRATION U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE NATIONAL INSTITUTES OF HEALTH U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES CONCERNING LABORATORY ANIMAL WELFARE

I. PURPOSE

The participating agencies share a common concern for the care and welfare of laboratory animals used in research and testing. Each agency, operating under its own authority, has specific responsibilities for fostering proper animal care and welfare. This agreement sets forth a framework for reciprocal cooperation which will assist each agency in meeting its responsibilities in promoting proper laboratory animal care and welfare. Implementation of this agreement is intended to maintain and enhance agency effectiveness while avoiding duplication of efforts to achieve required standards for the care and use of laboratory animals.

II. AGENCY RESPONSIBILITIES

Animal and Plant Health Inspection Service, USDA

Primary responsibility for the Animal Welfare Act (AWA) is assigned to the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). Implementing regulations of the AWA are established in the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Parts 1, 2, and 3. The Department has regulatory responsibility to enforce the implementing regulations. The USDA regulations establish standards for the humane treatment of laboratory animals and a registration/licensing procedure for identifying institutions that breed, sell, transport, hold, and use such animals. Compliance with the USDA regulations is monitored by an active inspection program that provides for periodic inspections by veterinary medical officers or suitably trained paraprofessionals. Serious noncompliance is dealt with by procedures that range from civil penalties, to the issuance of "cease and desist" orders, to the confiscation of animals.

Food and Drug Administration, HHS

The Food and Drug Administration (FDA) is also involved in ensuring proper procedures for the care and use of laboratory animals. The source statute is the Federal Food, Drug, and Cosmetic Act as implemented by the Good Laboratory Practice Regulations (21 CFR Part 58). These regulations establish standards for the proper conduct of non-clinical laboratory studies that include animals. Compliance is assessed through an active program of periodic inspections carried out by trained field inspectors. Serious noncompliance is dealt with by procedures ranging from study rejection to laboratory disqualification.

National Institutes of Health, HHS

The Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research, National Institutes of Health (NIH), is responsible for the implementation and general administration of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy implements the Health Research Extension Act of 1985 (Public Law 99-158), and is based on the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. Standards for institutional programs and facilities are described in the Guide for the Care and Use of Laboratory Animals. Institutions receiving PHS support must have an OLAW approved Animal Welfare Assurance that describes the institutional program and sets forth institutional compliance with PHS Policy. OLAW fosters compliance through the Assurance mechanism and a national education program, and monitors compliance by evaluating institutional reports of noncompliance. Institutions are required to correct confirmed noncompliance and institute appropriate measures to prevent repeated noncompliance. Potential sanctions for continued noncompliance appear in the NIH Grants Policy Statement, Part II, under authority derived from 45 CFR § 74.14 and 42 CFR § 52.9.

III. SHARED CONCERNS

USDA, FDA, and NIH share a common concern for the care and use of laboratory animals, although there are necessary operational differences among the animal welfare programs of the cooperating agencies. Congress acknowledged the need for transagency cooperation in the AWA by calling for the Secretary of Agriculture to consult and cooperate with other Federal departments and agencies concerned with the welfare of animals used in research, and to consult with the Secretary of Health and Human Services prior to the issuance of regulations.

Common program features include the promulgation of standards and policies aimed at promoting laboratory animal welfare, the maintenance of registries/inventories of institutions and facilities subject to agency policies and regulations, the periodic conduct of routine and "for cause" inspections or site visits, efforts designed to promote voluntary compliance, and the application of a range of sanctions when necessary.

Interagency cooperation provides an excellent opportunity to bolster individual agency efforts, achieve program benefits, and facilitate program operations. A mutually shared perspective on acceptable standards of laboratory animal care presents a consistent Federal approach and fosters compliance by regulated entities.

IV. SUBSTANCE OF AGREEMENT

The cooperating agencies agree to share information of mutual concern and interest regarding animal welfare. Specific agency responsibilities under this Memorandum of Understanding are detailed below.

A. The cooperating agencies agree to share information contained in their respective registries/inventories/listings of organizations that fall under their purview.

B. The cooperating agencies agree to provide one another with information concerning significant adverse findings regarding animal care and use at organizations investigated, inspected, or site-visited, and the actions taken by the agency in response to the findings.

C. The cooperating agencies agree to provide one another with information regarding evidence of serious noncompliance with required standards or policies for the care and use of laboratory animals at organizations that fall under the authority of the participating agencies.

D. The cooperating agencies agree, to the extent possible, to coordinate successive evaluations and to avoid redundant evaluations of the same entities.

E. The cooperating agencies agree to consult and coordinate with each other on regulatory or policy proposals and significant policy interpretations involving animal care and use under consideration by each agency.

F. The cooperating agencies agree to provide each other with resource persons for scientific and educational seminars, speeches, and workshops related to laboratory animal welfare.

G. The cooperating agencies agree to limit the dissemination of shared information received to internal agency officials that have a need to know. If a cooperating agency receives a Freedom of Information Act request for records provided by another agency, the recipient agency will refer the request to the agency that provided the records. The recipient agency shall promptly notify the agency that provided the information of any judicial order that compels the release of information.

V. STANDING COMMITTEE

To facilitate implementation of this agreement, the cooperating agencies each agree to designate a liaison officer to serve on a standing committee that will meet as needed, but no less than twice per year. Matters for consideration by the standing committee are to include a review of each agency's participation in this agreement, an assessment of the agreement's effectiveness, and modifications that might be necessary. As appropriate, the committee will address urgent issues and specific cases of serious noncompliance.

VII. LIAISON OFFICERS

For the Animal and Plant Health Inspection Service:

Chester Gipson, D.V.M.
Deputy Administrator
USDA, APHIS, AC
4700 River Road, Unit 97, Room 6A16
Riverdale, Maryland 20737-1234
Phone: 301-734-4980
Fax: 301-734-4993

For the Food and Drug Administration:

Rodney T. Allnutt
Consumer Safety Officer
Office of Enforcement, Office of Regulatory Affairs
U.S. Food and Drug Administration
Rockville, Maryland 20857
Phone: 240-632-6848
Fax: 240-632-6861

For the National Institutes of Health:

Carol Wigglesworth
Acting Director, Office of Laboratory Animal Welfare
Office of Extramural Research
National Institutes of Health
RKLI, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Phone: 301-496-7163
Fax: 301-402-2803

VIII. PERIOD OF AGREEMENT

This agreement becomes effective on the date of last signature and continues for 5 years. It may be modified by mutual written consent of the three parties. The agreement may be terminated by any party upon a 90-day advance written notice to the other parties. At the conclusion of 5 years the three parties will consider the development of a new agreement.

IX. ACCEPTANCE AND APPROVAL OF AUTHORIZING OFFICIALS

For the Animal and Plant Health Inspection Service, USDA:

Signature:

Name: W. Ron DeHaven, D.V.M.

Title: Administrator, Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Date: Feb 14, 2006

For the Food and Drug Administration, HHS:

Signature:

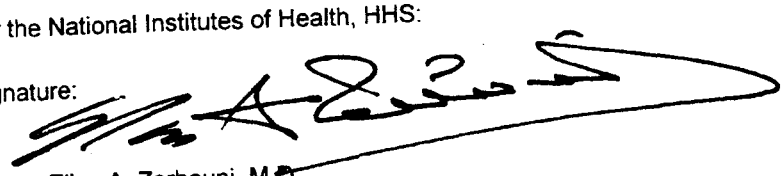
Name: Andrew C. von Eschenbach, M.D.

Title: Acting Commissioner of Food and Drugs
U.S. Department of Health and Human Services

Date: 2/2/06

For the National Institutes of Health, HHS:

Signature:



Name: Elias A. Zerhouni, M.D.

Title: Director, National Institutes of Health
U.S. Department of Health and Human Services

Date: 1/30/06

[FR Doc. 06–4184 Filed 5–2–06; 8:45 am]
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