distributing educational materials, and supporting activities that advocate preventing hepatitis B virus (HBV) infection through vaccination, education, testing, and treatment.

The Coalition's information and educational efforts are disease specific and its mission is to improve hepatitis B vaccination coverage levels and reduce the incidence of HBV infection. These activities are national in scope and are not limited to local or regional entities.

2. This Coalition is the only such organization whose primary objective is to provide hepatitis B information and education to health care providers to improve their immunization practices, and to the public to increase awareness and knowledge of the disease. The Coalition has also demonstrated success in reaching Southeast Asian communities, a high risk group that has not received culturally appropriate education, outreach, and testing/vaccination services from other health care providers. In addition, the Coalition has developed and tested effective bilingual educational materials for Asian/Pacific Islanders based on their cultural, religious, and political beliefs.

3. The Coalition has a demonstrated history of regular written communications such as newsletters or ''Dear Colleague'' letters. It has sponsored and promoted regularly scheduled local, regional, and national meetings of its individual members to share information, transfer skills, and promote initiatives pertaining to the prevention of HBV infection. It successfully motivates other organizations to participate in Coalition activities.

4. Through emphasis on public and provider education concerning hepatitis B prevention issues, the Coalition has demonstrated leadership in building relationships with national organizations, private and public sector non-profit health care organizations, professional health associations, volunteer groups, advocacy groups, minority organizations, and government entities.

No other organization devoted to addressing the wide-ranging needs for education and professional development on hepatitis B prevention exists that has the experience and demonstrated program successes, the national reach, and the organizational structure to provide to those audiences who will benefit the most, the information and education required to improve vaccination coverage levels and reduce disease incidence. The past performance and ongoing success of this Coalition make it uniquely qualified for this project.

Executive Order 12372

This applicant is not subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number for this project is 93.185.

Where To Obtain Additional Information

If you are interested in obtaining additional information about this project, please reference Announcement Number 538, and contact Lisa Tamaroff, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS E–13, Atlanta, GA 30305, telephone (404) 842–6796.

A copy of Healthy People 2000 (Full Report; Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report; Stock No. 017–001–00473–1) may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 3, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95–11351 Filed 5–8–95; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[FDA 225–94–6001]

Memorandum of Understanding Between the Food and Drug Administration and the National Institute of Standards and Technology

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Institute of Standards and Technology (NIST). The purpose of the MOU is to collaborate in a program to develop standard reference materials (SRM's) for a variety of biomaterials.

DATES: The agreement became effective February 14, 1994.

FOR FURTHER INFORMATION CONTACT: Sandy Cordes, Center for Devices and Radiological Health (HFZ–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3516.

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

Dated: May 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

Memorandum of Understanding Between the National Institute of Standards and Technology and the Food and Drug Administration, November 10, 1993

This memorandum of understanding (MOU) between the U.S. Department of Commerce, National Instituite of Standards and Technology (NIST) and the U.S. Department of Health and Human Services, Food and Drug Administration (FDA) has been implemented to facilitate the development of Standard Reference Materials (SRMs) for materials used in medical implant applications. These materials are commonly referred to as biomaterials.

Background

The National Institute of Standards and Technology has, as one of its long-standing programs, the development of and marketing of standard reference materials required for precision metrology in a variety of applications. The Food and Drug Administration is responsible for the regulation of medical devices made from biomaterials. For many of these biomaterials, it has been determined that subtle variations in chemical composition, trace element content, crystalline structure or morphology, homogeneity, surface topology and chemistry, and other material characteristics can significantly alter the response of living tissue (i.e. the body) to a material, either as an implant or by external contact. Thus the availability of well-characterized reference materials for use in generating baseline data on the biological performance of a biomaterial, is essential.

Overview

The parties to this MOU will collaborate in a program to develop (SRMs) for a variety of biomaterials. This collaboration will enable NIST to enhance its activities in the biomedical area and increase the utility of its SRM Program by addressing many critical measurement needs in the assessment of biomaterials and medical devices. The SRM Program at NIST will gain marketable SRMs for biomaterials, an area in which NIST has had no previous products. At the same time,

FDA will be assuring the availability of well-characterized and uniform reference materials for the comparative evaluation of new materials and devices. Evaluation of biological performance data based on comparison to previously-used and successful products will be both facilitated and improved.

Program Description

1. Selection of Materials—Candidate materials for SRM development will be selected by mutual agreement between FDA and NIST. The goal is to provide more realistic calibration standards for the determination of physical, chemical, electrical, and biological characteristics and/or properties of biomaterials. Criteria for selection will include magnitude of the current or potential utilization of the material in biomedical applications, documented or reasonably foreseeable variability in response from ''off-the-shelf'' materials, criticality of the medical application, cost of developing and potential market for the SRM, and others mutually agreeable to both parties. At the time of selection, the properties and characteristics to be controlled and measured will be identified for each candidate SRM, as will be the proposed unit size for distribution.

1.a An initial listing of candidate materials proposed at the time of the initial agreement is given in Appendix A. Materials 1 & 2 were developed as a collaborative research iniative between FDA and the American Dental Association (ADA) at both the FDA and NIST laboratories. Material 1 has been provided to NIST for consideration as an SRM. Material 2 which is currently being synthesized will be provided on or about September 1993. No development work has been done on materials 3–8.

2. Production of Materials—SRMs will be developed by any of several laboratories, including NIST, FDA, NIH, commercial materials suppliers, device manufacturers, academic institutions, and others. A Material Safety Data Sheet (MSDS) will be required from the supplier of all component materials and precursor/catalyst/ancillary materials used in the production of SRMs developed under this MOU.

3. Certification—NIST will determine and specify what testing must be performed and be the sole reviewer of the adequacy of data used in the qualification of SRMs developed under this MOU. NIST reserves the right to refuse distribution of materials if the data are inadequate. All SRMs developed under this program will be supplied with NIST certification for the properties/characteristics deemed critical to the application.

4. Packaging—NIST will determine for each SRM the appropriate source of packaging, either in-house or contract. Contract packagers will seal the entire shipment in appropriate packages for shipment to NIST.

5. Replenishment—NIST agrees to assume the responsibility for replenishment of stocks for SRMs for which the market is at a level that is financially beneficial to the Standard Reference Materials Program.

6. Program Funding—FDA does not commit to providing any funding or equipment to NIST or any selected SRM producer, or to providing any laboratory effort in the development, characterization, or production of SRMs being developed under this program.

Costs and Pricing

1. Initially, FDA will provide 900 grams of hydroxyapatite (material 1, Appendix A) and 1000 grams of β-Tricalcium Phosphate (material 2, Appendix A) to NIST for use as an SRM. No compensation to FDA is required for this initial supply of material. Monies collected from the sale of the SRMs, which is over and above the cost to produce, characterize and package the materials will be used for additional SRM development.

2. NIST will have final authority over all matters pertaining to pricing policy and for setting the price of individual SRMs.

General

1. SRMs developed in whole or in part by FDA prior to or under this MOU, which remain unsold and are deemed by NIST, to be technologically obsolete or otherwise no longer acceptable as SRMs, may be removed from the NIST inventory without liability for reimbursement to FDA by NIST. If FDA desires such products returned to FDA, NIST will do so at FDA's expense after removal of SRM certification.

2. The official representatives of the respective organizations will be:

FDA: Director Division of Mechanics and Materials Science Office of Science and Technology Center for Devices and Radiological Health

NIST: Chief Standard Reference Materials Program Office of Measurement Services

Effective Dates

1. This MOU will become effective 30 days after being signed by the appropriate authorities at both NIST and FDA. It will remain in effect until terminated.

2. Either NIST or FDA may unilaterally terminate this MOU by providing the other party written notice. It will become ineffective 60 days after such notice is delivered.

Approval/Acceptance

Signed:
D. Bruce Burlington, M.D.
Director, FDA/CDRH
Date: November 19, 1993

Approved:
Peter L.M. Heydemann, PhD.
Director, NIST/Technology Services
Date: January 14, 1994

Concur:
Thomas E. Gills
Chief, NIST/SRMP
Date: January 14, 1994

Appendix A

Purpose:

Development of a series of Calcium-Phosphorous based SRMs for use in determining the composition of mixtures of calcium phosphate based biomaterials or biomaterial coatings.

Proposed Calcium Phosphate Reference Biomaterials

1. $Ca_3(PO_4)_3OH$	Hydroxyapatite	Ca/P=1.67
2. $Ca_3(PO_4)_2$	Tricalcium Phosphate (β)	Ca/P=1.50
3. $Ca_3(PO_4)_2$	Tricalcium Phosphate (amorphous)	CA/P=1.50
4. $Ca_4(PO_4)_2O$	Tetracalcium Phosphate	CA/P=2.0
5. $Ca_3(PO_4)_2$	Tricalcium Phosphate (α)	CA/P=1.50
6. $Ca_2P_2O_7$	Calcium Pyrophosphate (α β γ)	CA/P=1.0
7. CaO	Calcium Oxide	NA
8. $Ca_{10}(PO_4)_5F_2$	Fluorapatite	CA/P=1.67

[FR Doc. 95–11415 Filed 5–8–95; 8:45 am]

BILLING CODE 4160–01–F

[FDA–225–94–6000]

Memorandum of Understanding Between the Food and Drug Administration, the Uniformed Services University of the Health Sciences, and the National Naval Medical Center

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA, the Uniformed Services University of the Health Sciences, and the National Naval Medical Center. The purpose of the MOU is to establish an agreement in support of a clinical investigation program study entitled ''Prevention of Photochemical Retinal Injuries During Extracapsular Cataract Surgery.''