DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Memorandum of Understanding Between the Food and Drug Administration and the National Institutes of Health's National Institute of Dental Research

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 the National Institutes of Health's National Institute of Dental Research (NIDR) and three of FDA's line organizations: the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research. The purpose of the MOU is to facilitate interactions between NIDR and FDA regarding improvements in the quality and relevance of preclinical and clinical research, which is directed to the development of products for use in oral healthcare.

DATES: The agreement became effective August 10, 1997.

FOR FURTHER INFORMATION CONTACT:

Susan Runner, Center for Devices and Radiological Health (HFZ–410), 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879, or

Norman S. Braveman, National Institute of Dental Research, National Institutes of Health, 45 Center Dr., MSC 6400, Bldg. 45, rm. 4AN–24, Bethesda, MD 20892–6400, 301–594–2089.

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

Dated: May 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

225–97–6000

Memorandum of Understanding Between the National Institutes of Health, National Institute of Dental Research and the Food and Drug Administration, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research

I. Purpose

This Memorandum of Understanding hereby establishes a formal collaborative arrangement between the National Institutes of Health's National Institute of Dental Research (NIDR) and three of the Food and Drug Administration's (FDA) line organizations: Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER).

This agreement has been developed to facilitate interactions between the NIDR and the FDA regarding improvements in the quality and relevance of pre-clinical and clinical research which is directed to the development of products for use in oral health care. The principal goal of this agreement is to reduce the time between the research and development phase of a product's life cycle and its commercial availability. This goal will be attained by enhancing the quality of product-related research and thus facilitate and improve premarket evaluations.

This agreement also sets forth certain working arrangements between both parties that will enable each to fulfill its respective mission more efficiently and effectively.

II. Background

It is widely accepted that the United States has a world-class health care system. This status is due in part to entrepreneurship and capital investment in the private sector. It is also the result of our nation's longstanding commitment to Federally-funded research into health promotion, disease prevention, diagnosis, etiology and pathogenesis, as well as cost-effective therapeutic approaches for varied and complex health conditions. A third contributing factor is the existence of a vigilant national regulatory system that ensures health professionals and consumers are provided with safe, high quality and clinically viable medical products. Despite the reputation of the U.S. system, however, government agencies with responsibility for the development, promotion and regulatory oversight of new medical products are today, as always, striving to eliminate operational inefficiencies that can act as barriers to the development of new technologies and therapeutics and their timely introduction into the marketplace. Leaders throughout the government sector have intensified efforts to sharpen current modes of business as a means to economize, to insure the expenditure of public funds will yield commensurate public benefits, and to enable the Federal government to better serve the contemporary needs of its constituencies.

Increasingly in recent years, NIDR and FDA component organizations have harnessed their interdisciplinary skills and professional expertise in a number of areas affecting the public health. Although complementary and beneficial, these interactions have largely been ad hoc and informal. Leaders of both agencies have recognized the added benefits that can accrue from a broader, more formal working arrangement. To this end, this agreement establishes a generalized, cooperative framework with end-goals and categories of activities that, taken together, provide the foundation for a working relationship that is better focused and takes fuller advantage of each organization's strengths and experience.

III. Substance of Agreement

As noted above, this agreement charts a general course of interaction between the NIDR and three of FDA's product centers that encompasses the following areas:

(A) information exchange;
(B) state-of-the-science workshops and conferences;
(C) staff development;
(D) fellowship sponsorship;
(E) policy development;
(F) research; and
(G) advisory committee and study section review and appointments.

The ''Implementation Work Plan'' attached to this agreement identifies the range of specific projects and activities that fall within each of the seven categories. The Work Plan also provides a narrative description of the commitments made by each of the signatory agencies and specifies relative priorities and projected implementation timeframes, which are subject to change during the period when this agreement is in effect.

Both parties envisage this agreement and its components to be implemented on an evolutionary and incremental basis in accordance with available organizational resources and mutual determination of the feasibility and anticipated benefit(s) of individual activities. Moreover, both parties have agreed that whenever appropriate and possible, interagency activities—either on a categorical or individual basis—should be periodically evaluated to confirm that the putative benefits in relation to administrative costs and other considerations justify continuation or expansion of the activities specified in this agreement. Evaluation of this pioneering agreement may also serve to establish the basis for similar collaborative arrangements between other NIH Institutes and FDA in the future.

IV. Name and Address of Participating Parties

(1) National Institute of Dental Research, National Institutes of Health, 31 Center Drive, MSC 2290, Building 31, 2C39 Bethesda, MD 20892–2290, Telephone: 301–496–3571, FAX: 301–402–2185.

(2) Food and Drug Administration (HF–1), 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–827–3310, FAX: 301–443–3100.

(a) Center for Devices and Radiological Health (HFZ–1), 9200 Corporate Boulevard, Rockville, MD 20850, Telephone: 301–443–4690, FAX: 301–594–1320.

(b) Center for Drug Evaluation and Research (HFD–1), 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301–594–6740, FAX: 301–594–6197.

(c) Center for Biologics Evaluation and Research (HFM–1), 8800 Rockville Pike, Bethesda, MD 20892–001, Telephone: 301–827–0548, FAX: 301–827–0440.

V. Liaison Officers

For the National Institute of Dental Research:

Dushanka V. Kleinman, D.D.S., M.Sc.D., Deputy Director, National Institute of Dental Research, National Institutes of Health, 31 Center Drive, MSC 2290

Building 31, Room 2C39, Bethesda, MD 20892–2290, Telephone: 301–496–9469, FAX: 301–402–2185, E-mail: KLEINMAND@OD31.NIDR.NIH.GOV

Lois K. Cohen, Ph.D., Alternate Director, Division of Extramural Research, National Institute of Dental Research, National Institutes of Health, 45 Center Drive, MSC 6400, Building 45, Room 4AN–18, Bethesda, MD 20892–6400, Telephone: 301–594–7710, FAX: 301–480–8319, E-mail: COHENL@DE45.NIDR.NIH.GOV

For the Food and Drug Administration:

Bernard A. Schwetz, D.V.M., Ph.D., Interim Chief Scientist, Office of the Commissioner (HF–32), Food and Drug Administration, 5600 Fishers Lane, Room 17–35, Rockville, MD 20857, Telephone: 301–827–3340, FAX: 301–827–3042, E-mail: BSCHWETZ@NCTR.FDA.GOV

Elizabeth D. Jacobson, Ph.D., Alternate Deputy Director for Science, Center for Devices and Radiological Health (HFZ–2), 9200 Corporate Boulevard, Room 100G, Rockville, MD 20850, Telephone: 301–443–4690, FAX: 301–594–1320, E-mail: EDJ@CDRH.FDA.GOV

VI. Interagency Steering Committee

To assist the Liaison Officers in the management, coordination and oversight of this agreement and the concomitant Implementation Work Plan, an interagency steering committee shall be established. The Committee will be comprised of an equal number of member representatives from the NIDR and FDA, including the Liaison Officers who shall serve as co-chairs of the Committee. Member appointments shall be authorized by the signatories to this agreement and shall last for a period of one (1) year, unless renewed by the agreement signatories upon recommendation from the Liaison Officers. The Committee shall meet at least once every six months for the first year of this agreement and then at least once annually thereafter to review the progress of this agreement, resolve any issues and disputes that may arise, re-direct specific activities set forth in the Work Plan, and oversee necessary modifications to the agreement.

As of the date this agreement is approved and accepted, the following persons are designated to serve on the Committee for the initial one-year term.

For the National Institute of Dental Research:

Dushanka V. Kleinman, D.D.S., M.Sc.D., Co-Chair

Lois K. Cohen, Ph.D., Alternate

Norman S. Braveman, Ph.D., Chief, Program Development Branch, Division of Extramural Research, National Institute of Dental Research, National Institutes of Health, 45 Center Drive, MSC 6400, Building 45, Room 4AN–24, Bethesda, MD 20892–6400, Telephone: 301–594–2089, FAX: 301–480–8318, E-mail: BRAVEMANN@DE45.NIDR.NIH.GOV

Henning Birkedal-Hansen, D.D.S., Ph.D., Scientific Director, Division of Intramural Research, National Institute of Dental Research, National Institutes of Health, 30 Convent Drive, MSC 4326, Building 30, Room 132, Bethesda, MD 20892–4326, Telephone: 301–496–1483, FAX: 301–402–8318, E-mail: HBHANSEN@IRP30.NIDR.NIH.GOV

For the Food and Drug Administration:

Bernard A. Schwetz, D.V.M., Ph.D., Co-Chair

Elizabeth D. Jacobson, Ph.D., Alternate

Michael Weintraub, M.D., Director, Office of Drug Evaluation V (HFD–105), Center for Drug Evaluation and Research, 9201 Corporate Boulevard, Room S219, Rockville, MD 20850, Telephone: 301–827–2250, FAX: 301–827–2317, E-mail: WEINTRAUB@CDER.FDA.GOV

Philip D. Noguchi, M.D., Director, Division of Cellular and Gene Therapies (HFM–515), Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, 8800 Rockville Pike, Building N29B, Room 2NN20, Bethesda, MD 20892–001, Telephone: 301–827–0680, FAX: 301–827–0449, E-mail: NOGUCHI@CBER.FDA.GOV

VII. Period of Agreement

Upon acceptance by both parties, this agreement will become effective immediately and remain in effect for a period of three (3) years from the date of signature by authorized officials from both agencies unless extended by the parties. The terms of this agreement may be modified upon mutual written consent, or terminated by either party with a minimum 30-day advance written notice to the other party. Evaluation of the terms and success of this agreement will be made periodically throughout the existence of the interagency arrangement. Within ninety (90) days prior to expiration of this agreement, a formal written evaluation shall be prepared by both parties and submitted to appropriate officials of both agencies with recommendations regarding the furtherance or discontinuation of the agreement.

VIII. Funding

No funding will be provided or exchanged by either party as part of this agreement. NIDR and FDA personnel will collaborate on projects of mutual interest. Facilities and equipment of each party will be made available to the other on an as needed basis in accordance with the individual project and activity plans and arrangements.

IX. Reporting Requirements

In addition to the evaluation report(s) referenced in section VII. above, reporting responsibilities will be determined on a case-by-case basis and as required by individual projects and activities. Reports will be provided to all Liaison Officers named in this agreement.

X. Schedules and Milestones

Schedules and milestones for all collaborative projects and activities authorized by this agreement will be developed by mutual agreement on a case-by-case basis. Schedules and milestones may be set by interagency working groups established and tasked to implement the specific projects and activities outlined in the Implementation Work Plan appended to this agreement.

XI. Disposition of Data

The plan for each project and activity set forth in the Implementation Work Plan as appended to this agreement will specify the disposition of data and other information that may result from or be used during the course of a project or activity. Publication or public dissemination of data and information exempt from public disclosure under applicable law shall not occur without prior notification and concurrence of the Liaison Officers of both parties.

XII. Sharing Data and Information

Both parties agree that a free exchange of data and information is vital to the successful execution of this agreement. Therefore, to the extent allowed under 21 U.S.C. 331(j), 21 U.S.C. 360j(c), 42 U.S.C. 353g(d), 42 U.S.C. 263i(e), 21 CFR Part 20, or other applicable law, the parties agree to share data and information as necessary. No exchange of non-public information will occur unless appropriate safeguards are established and set forth in individual work plans and first approved by the agencies' Liaison Officers.

XIII. Disclosure of Data and Information in Response to Requests

If disclosure of data or information received by a party under this agreement is requested under the Freedom of Information Act, a Congressional inquiry or pursuant to other duties and responsibilities of either party to this agreement, the agency that receives the request shall notify the agency that provided the information. The notified agency will be responsible for making any requisite contact with the submitter of the protected information and will accept full responsibility for evaluating the submitter's comments prior to rendering a disclosure determination.

To preserve maximum control over actual disclosure of their respective records, each party to this agreement shall retain legal authority and the concomitant responsibility regarding disclosure of documents provided to the other agency.

XIV. Government Property/Facilities/Personnel

Both parties to this agreement will make available personnel and facilities as required by individual projects and activities as set forth in the mutually developed work plans. NIDR personnel enlisted to serve as Federal consultants or liaisons on FDA advisory committees and panels will be subject to the same rights, privileges, obligations and restrictions as all other special government employees who serve on the agency's advisory bodies. Similarly, all FDA employees selected to serve in a consultative capacity on NIDR research study sections and advisory bodies will be bound by the same rules and allowances that apply to all other consultants appointed by NIDR.

Approved and Accepted for the National Institute of Dental Research:

By: Harold C. Slavkin, D.D.S.

Title: Director, National Institutes of Dental Research, NIH

National Institutes of Health

Date: August 1, 1997

Approved and Accepted for the Food and Drug Administration:
By: Michael A. Friedman, M.D.
Title: Lead Deputy Commissioner
Food and Drug Administration
Date: August 10, 1997

Appendix: Implementation Work Plan

Appendix

Implementation Work Plan for Memorandum of Understanding Between the National Institute of Dental Research and the Food and Drug Administration

Introduction

The National Institute of Dental Research (NIDR) and the Food and Drug Administration (FDA) have embarked upon a formal collaborative arrangement whose dual aims are to: (1) facilitate the development and market introduction of newly-emerging, safe and effective health care products to enable oral health professionals and auxiliaries to provide higher quality services and equip consumers with the tools necessary to improve and sustain their own oral, dental and cranio-facial health; and (2) provide complementary support and expertise to enable each agency to better fulfill its public health mission.

This Implementation Work Plan describes the specific projects and activities that initially constitute the substance of the collaborative arrangement between the two agencies. The information that follows is intended to serve as an overall work plan or framework for NIDR and FDA personnel assigned individual projects and activities. The specific outcomes, completion timeframes, interaction mechanisms, etc. associated with each project and activity will be defined by those persons designated by each agency to serve on interagency working groups. The relative priority of each project/activity is identified by the use of the letters ''I'' (immediate— within 3 mos.), ''S'' (short-term—within 6–12 mos.), and ''L'' (long-term—beyond 12 mos.).

A. Information Exchange

In this area of collaboration, NIDR and FDA agree to pursue the following activities:

- Initiation of an ongoing series of introductory meetings and orientation briefings to acquaint NIDR and FDA personnel with each other's statutory obligations, programs, operational capacities, policies, processes, etc. that are relevant to this agreement. [I]
- Identification of key contact persons at each agency and preparation of a contact/referral directory to facilitate interagency communication and information exchange. [I]
- Establishment of a hyperlink between existing FDA and NIDR Internet websites to permit continual and instantaneous access to routine and late-breaking information of mutual interest. [I]
- Establishment of an internal exchange forum to enable a periodic two-way sharing of information related to new research initiatives by both agencies, market applications for important new products pending with FDA, emerging public health issues and emergencies and policy development. Biomimetics is a case in point and could be used as a case study to identify optimal methods for both parties to monitor an issue from the conceptual stage through research and development. [S]
- Creation of a ''Oral, Dental and Cranio-Facial Forum'' in which NIDR and FDA can interact periodically with leading representatives of the regulated industry, academia, the research community and others on issues relating to technology development and transfer (including regulatory processes for acquiring market clearance), product utilization and treatment outcomes, adverse event reporting, etc. [S]
- Assessment of the viability of NIDR and/or FDA experts serving as Federal ''ombudsmen'' to oversee state-of-the-art advances in oral, dental and cranio-facial technologies and therapeutics through direct, ''in the field'' interactions with clinical investigators, product developers, scientific researchers, etc. The ombudsmen would act as conduits through which regulatory process and research funding information could be funneled to the industrial and research sectors. Information on emerging products, in both the concept and development stage, could in turn be fed back to NIDR and FDA with the end goal of accelerating the flow of new products that are safe and effective from the R&D arena to the clinical environment. [L]

This feasibility assessment could also encompass the concept of an ombudsman or independent, non-government expert(s) conducting an evaluation of a sampling of dental products whose basic research costs are underwritten by NIDR that traces the developmental histories through patent acquisitions and FDA market clearances. The purpose of such evaluations would be to augment the existing patient evaluation study by providing documentation of selected impact(s) of NIDR-funded research on public health and the ''bench-to-chairside'' delivery of important new oral care products. [L]

B. Science Transfer & State-of Science Workshops/Conferences

- Participation by FDA regulatory policy-makers and program officials in various conferences in 1997–98 sponsored by NIDR or in which NIDR has a planning/participant role. FDA involvement could entail formal workshops (e.g., FY99 meeting of AADR/AADS meeting), individual presentations, use of existing videotaped FDA teleconferences on selected regulatory policy and process issues, technology transfer, etc. In addition, NIDR staff will participate in FDA-sponsored workshops and conferences with relevance to oral and dental health care products and services. Collaborative discussions and planning between NIDR and FDA could serve to focus the form and content of information conducive to each presentation setting and ensure proper coverage by both agencies at key outside conferences and meetings. [I/S]
- Development and joint sponsorship of conferences, symposia and workshops whose foci and outputs will mutually benefit NIDR and FDA, e.g., in the area of technology transfer. [S/L]
- Review of the feasibility and utility of live, jointly-produced videoteleconferences using FDA/CDRH and/or NIDR facilities to communicate to each agency's constituencies on topical areas of interest, fast-moving events, new research and regulatory initiatives, etc. [S]
- Development, pilot testing and nationwide dissemination of a regulatory training module for U.S. dental school instructors, dental students, clinical trial sponsors and investigators to broaden their understanding of FDA's market clearance requirements and product evaluation processes. [L]

C. Staff Development and Collaborations

- Arrange for the temporary exchanges of NIDR and FDA specialists for pre-set periods of time (e.g., 6–12 months). These cross-appointments, which could include rotation of FDA scientists and clinicians through the NIH Clinical Center where research is performed, could enhance the understanding of each party to the policies and procedures of the other. This cross-fertilization of knowledge and experience could subsequently be shared with in-house colleagues and outside constituent groups in ways that could expedite technology transfer. [S]
- Provide for FDA scientists and regulatory process experts to participate in NIDR reviews of research applications (e.g., SBIR/STTR) as a means of gaining insights into future research and product development directions, which in turn would enable FDA product reviewers to better anticipate and prepare for scientific and clinical issues associated with future product applications. [S]
- Provide for NIDR experts to directly participate in premarket evaluations of selected new dental products whose scientific and clinical aspects may be complex or controversial, in addition to submissions seeking FDA authorization to conduct clinical studies involving experimental products. [S]
- Involvement of NIDR experts in a ground-breaking initiative relating to FDA's review process for medical devices, specifically the Product Development Protocol, a mechanism authorized by Federal law by which FDA and device producers can reach agreement at the front end of the premarket review process on test endpoints that, once satisfied, provide for a higher degree of assurance (but no guarantee) of market clearance. Resident scientific and clinical expertise at NIDR could be relied upon as this mechanism is pilot tested and in actual ''negotiations'' with product manufacturers and study sponsors. [S]
- Development of reference documents describing FDA investigational product and market approval processes for use by NIDR reviewers in conferring with prospective research grantees and contractors to better assure their clinical studies conform to FDA marketing requirements, which will help spur the clinical availability of valuable new products. Such documents could be adaptations of the regulatory training module discussed in Section B. of this document. [S]
- Evaluation of the feasibility of NIDR requiring prospective research contractors

and grantees, as a condition for a funding award, to submit review protocols or criteria that FDA can use in performing premarket reviews of breakthrough products used in the prevention, diagnosis and treatment of oral, dental and cranio-facial diseases and conditions. [S]

• Investigation into methods by which NIDR and FDA can jointly and individually promote the availability and use of FDA's adverse incident reporting systems (e.g., MedWatch) among oral health professionals and other health and dental product user groups. [S]

• Enlistment of NIDR technical, statistical and clinical experts to assist FDA in the design and content development of guidance documents that FDA product reviewers can use to assess product safety and effectiveness. [L]

D. Fellowship Sponsorship

• Investigation into the merits and legal aspects of establishing non-Federal fellowships in which interested parties from the private sector would subsidize individuals with an interest in FDA regulatory processes for one-year residency periods. Under such an arrangement, NIDR could serve as fiduciary in order to prevent appearances of conflict-of-interest. Fellowship assignments would entail generalized exposure to and experience with FDA regulatory procedures so as to also avoid access to protected, product-specific information that could be used for competitive advantage. Fellows would also be subjected to the controls, rights, privileges and restrictions to which all other FDA-recruited special government employees are subjected. [L]

E. Policy Development

• Continuation of current interchanges and expert consultations on selected policy issues that engender wide-scale interest among consumers and/or oral health professionals, involve products or therapies that pose a known or potential health risk to the general public, relate to research and regulatory processes affecting the pace of technology transfer, etc. This activity should extend to other matters of major import such as the Surgeon General's report on oral health which NIDR has been charged to produce and to which FDA can substantively contribute. [I]

F. Research

• Continuation of ongoing research collaborations, such as those between CBER and NIDR's Division of Intramural Research.

• Coordination of NIDR's biological and clinical resources and the CDRH's engineering and life sciences expertise to address a number of diverse issues relating to cleaning, infection and sensitivity reactions to new biomaterials. [S]

• Establishment of one or more patient registries for purposes of monitoring adverse incidents linked to particular dental products in addition to product-specific performance trends. Such an activity could be jointly undertaken by FDA and NIDR, as well as in conjunction with involvement by other organizations such as USP and various dental professional and product user organizations. [L]

• Initiation of collaborative research aimed at developing fundamental data and methods needed to assess long-term performance of dental devices and systems. Such research could include the joint development of physical, animal and computer-based models to adequately evaluate long-term clinical performance of marketed and evolving dental devices (e.g., osseous integration of dental implants, fatigue performance of ceramic porcelains, etc.). [L]

G. Advisory Committee & Study Section Review/Appointments

• Provision of ad hoc or liaison status to FDA officials on the NIDR National Advisory Dental Research Council (including access to closed sessions of the Council on a case-by-case, need-to-know basis), in addition to DRG and other study sections/review groups for the purpose of assisting NIDR in its review of extramural research submissions. [S]

• Expansion of current NIDR participation as consultants and/or Federal liaisons on dental-related advisory committees and panels managed by FDA (including access to closed sessions on a case-by-case, need-to-know basis) for the purpose of augmenting the scientific and clinical expertise that is brought to bear on product applications and proposed policies on which outside advice is sought by the agency. [S]

• Formal solicitation of advice by each party from the other on candidate nominations for appointment to NIDR and FDA review and advisory bodies. [S]

[FR Doc. 98–14462 Filed 6–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collections; Comment Request: National Institutes of Health Construction Grants

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* National Institutes of Health Construction Grants (42 CFR Part 52b). *Type of Information Collection Request:* Extension of OMB No. 0925–0424, expiration date 09/30/98. *Need and Use of Information Collection:* This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 52b. The purpose of the regulations is to govern the awarding and administration of grants awarded by NIH and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building) suitable for the purpose for which it was constructed. In terms of reporting requirements:

Section 52b.9(b) of the proposed regulations requires the transferor of a facility which is sold or transferred, or the owner of a facility, the use of which has changed, to provide written notice of the sale, transfer or change within 30 days. Section 52b.10(f) requires a grantee to submit an approved copy of the construction schedule prior to the start of construction. Section 52b.10(g) requires a grantee to provide daily construction logs and monthly status reports upon request at the job site. Section 52b.11(b) requires applicants for a project involving the acquisition of existing facilities to provide the estimated costs of the project, cost of the acquisition of existing facilities, and cost of remodeling, renovating, or altering facilities to serve the purposes for which they are acquired.

In terms of recordkeeping requirements: Section 52b.10(g) requires grantees to maintain daily construction logs and monthly status reports at the job site. *Frequency of Response:* On occasion. *Affected Public:* Non-profit organizations and Federal agencies. *Type of Respondents:* Grantees. The estimated respondent burden is as follows:

	Estimated annual reporting and recordkeeping burden			
	Annual number of respondents	Annual frequency	Average burden per	Annual burden hours
Reporting:				
§ 52b.9(b)	1	1	.50	.50