that it is seeking pharmaceutical companies to participate in a pilot program involving the submission of CMC information consistent with a new pharmaceutical quality assessment system. The Office of New Drug Chemistry (ONDC) in the Office of Pharmaceutical Science, Center for Drug Evaluation and Research, is establishing a modern, risk-based pharmaceutical quality assessment system, as described in a September 2004 White Paper, ''ONDC's New Risk-Based Pharmaceutical Quality Assessment System'' (*http://www.fda.gov/cder/gmp/gmp2004/ondc_reorg.htm*). The pilot program will provide additional information for ONDC to use in implementing the new quality assessment system. The pilot program will provide participating pharmaceutical companies an opportunity to submit critical CMC information that demonstrates their understanding of quality by design, product knowledge, and process understanding of the drug substance and drug product at the time of submission of an NDA. The pilot program will also enable the public and regulated industry to provide feedback that will assist FDA in developing guidance for industry on the new quality assessment system.

The July 14, 2005 (70 FR 40719), notice provided deadlines related to the submission of certain information related to the pilot program. To ensure inclusive and relevant results from the pilot program, this notice extends the deadlines as follows: Requests to participate in the pilot program to March 31, 2006, from October 31, 2005, and submission of eligible New Drug Applications (NDA) to March 31, 2007, from December 31, 2006. This notice also extends the comment period on the pilot program to March 31, 2007, from December 31, 2006. See the process section (II.B) in the July 14, 2005 (70 FR 40719) notice for instructions on submitting requests to participate in the pilot program. All requests to participate in the pilot program, both written and electronic, should be marked confidential.

II. Comments

Interested persons may submit written comments on this pilot program to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. While detailed information on participating NDAs will not be publicly available, names of participating applicants will be made public.

Dated: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18515 Filed 9–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–02–1000]

Memorandum of Understanding Between the Food and Drug Administration, Center for Biologics Evaluation and Research, and the National Institutes of Health, National Institute of Neurological Disorders and Stroke

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 Food and Drug Administration, Center for Biologics Evaluation and Research (FDA/CBER), and the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS). The purpose of this MOU is to provide a framework for coordination and collaborative efforts between these two entities, which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information sharing between FDA/CBER and NIH/NINDS units shall take place.

DATES: The agreement became effective February 12, 2002.

FOR FURTHER INFORMATION CONTACT: *For FDA/CBER*: Kimberly Benton, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, WOC1/rm. 209N, Rockville, MD 20852, 301–827–5102.

For NIH/NINDS: Robert Finkelstein, Extramural Research, Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., rm. 2143, Bethesda, MD 20892, 301–496–9248.

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: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

225-02-1000

MEMORANDUM OF UNDERSTANDING
Between the
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
and the
NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

I. PURPOSE

This Memorandum of Understanding (MOU) between the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) and the National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/ NINDS) provides a framework for coordination and collaborative efforts between these two entities, which are both components of the Department of Health and Human Services. This MOU also provides the principles and procedures by which information sharing between FDA/CBER and NIH/NINDS units shall take place.

II. BACKGROUND

FDA and NIH are sister agencies within the Department of Health and Human Services. Both FDA and NIH exist and work to protect the public health but have different statutory mandates and responsibilities.

FDA is a science-based regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, and medical products, including human drugs, biological products, animal drugs, and medical devices. FDA administers the Federal Food, Drug, and Cosmetic Act and relevant sections of the Public Health Service Act, among other statutes. Among its duties, FDA reviews and monitors the use of investigative articles in clinical studies, conducts on-site inspections of biomedical research, approves pre-market applications, conducts regulatory research, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events. FDA also refers civil and criminal cases to the Department of Justice to enforce applicable laws and regulations. Within FDA, CBER's mission is to protect and enhance the public health through regulation of biological and many combination products according to statutory authorities. The regulation of these products is founded on science and law to ensure their purity, potency, safety and efficacy.

The NIH is the Federal focal point for biomedical research in the United States. The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by conducting research in its own laboratories; supporting the research of non-Federal scientists in universities, medical schools, hospitals and research institutions throughout the country and abroad; helping in the training of research investigators; and fostering communication of medical information. Within the NIH, the NINDS is the nation's

leading supporter of biomedical research on disorders of the brain and nervous system. The mission of the NINDS is to reduce the burden of neurological disease. To achieve this mission, the NINDS conducts, fosters, coordinates and guides research on the causes, prevention, diagnosis and treatment of neurological disorders and stroke, including basic research in related scientific areas.

NIH's and FDA's respective missions to protect the public health are complementary and may overlap depending upon the subject matter. The agencies work collaboratively to protect and improve public health. Sometimes FDA/CBER or NIH/NINDS may have information that could be useful to the other unit in that unit's performance of its responsibilities. Timely sharing of information between NIH/NINDS and FDA/CBER is therefore critical to protect and improve the public health.

III. SUBSTANCE OF AGREEMENT AND RESPONSIBILITIES OF EACH AGENCY

A. *Coordination and Collaboration Relative to Public Health Activities*

It is mutually agreed that:

1. FDA/CBER and NIH/NINDS will coordinate and collaborate with each other to protect and improve the public health. To achieve this, each unit will utilize the expertise, resources, and relationships of the other in order to increase its own capability and readiness to respond to situations. In addition, each unit will designate central contact points to coordinate communications from the other, dealing with matters covered by this agreement.

2. Each unit will participate in periodic joint meetings to promote better communication and understanding of regulations, policies, and statutory responsibilities, and to serve as a forum for questions and problems that may arise.

3. Each unit will notify the other when issues of mutual concern become evident to the extent such notification does not interfere with the public health, oversight, enforcement, or compliance responsibilities of the notifying agency.

4. Each unit will work to execute the Implementation Work Plan *(Appendix)*

5. This agreement does not preclude NIH/NINDS or FDA/CBER from entering into other agreements which may set forth procedures for special programs which can be handled more efficiently and expertly by other agreements.

B. *Principles and Procedures for the Sharing of Non-Public Information*

FDA/CBER and NIH/NINDS agree that the following principles and procedures will govern the

sharing of non-public information between the two units.

FDA/CBER and NIH/NINDS agree that there should be a presumption in favor of full and free sharing of information between FDA/CBER and NIH/NINDS. As units of sister public health agencies within the Department of Health and Human Services, FDA/CBER and NIH/NINDS legally may share with each other most information in their possession, including non-public information in electronic databases. Both units recognize and acknowledge, however, that it is essential that any non-public information that is shared between FDA/CBER and NIH/NINDS whether in writing or orally must be protected from any disclosure that is not authorized by law or regulation. See e.g., 5 U.S.C. § 552; 5 U.S.C § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. Parts 20 and 21. Safeguards are important to protect non-public information shared, such as trade secrets and confidential commercial information; identities of study participants and other personal privacy information; privileged and/or pre-decisional agency information; research proposals, progress reports, and/or unpublished data; or information protected for national security reasons. Such safeguards also help ensure FDA/CBER's and NIH/NINDS's compliance with applicable laws and regulations.

To facilitate the sharing of non-public information with each other, FDA/CBER and NIH/NINDS are implementing procedures to ensure, at a minimum, that such sharing is indeed appropriate and that the recipient unit guards the confidentiality of all information received.[1] It is incumbent upon both units to respond to requests for information in a complete and timely manner, consistent with budgetary and resource constraints, and to the extent permitted by law, regulation or agency policy and practice. The unit receiving shared non-public information shall be responsible for protecting that information from any unauthorized disclosure. Additional information-sharing provisions, none of which shall preclude the sharing orally of non-public information in accordance with applicable statutes or regulations, are set out below:

1. The requesting unit must specify, in writing[2], the information requested (to facilitate identification of relevant information) and provide a brief statement of why the information is needed. This request shall state which internal unit offices and/or individuals are requesting the information. A model request letter is attached. Upon mutual agreement, FDA/CBER and NIH/NINDS may modify the request letter appropriately, e.g., to permit the sharing of related non-public information over a specified period of time.

2. The unit receiving the request shall, based upon the request described in section III B 1 above, determine whether it is appropriate to share the requested non-public information. For example, a unit should decide not to share information if it has credible information and a reasonable belief that the requesting unit may not be able to comply with applicable laws or

[1] It is assumed that each agency has implemented or will implement all data and information security statutory, regulatory, policy, or procedural requirements and has implemented or will implement, to the extent necessary and practicable, all data and information security recommendations suggested by the other agency.

[2] The term "writing" used throughout this MOU includes a writing by electronic means.

regulations governing the protection of non-public information or with the principles or procedures set forth in this MOU. If a unit decides not to share information, it shall describe to the requesting unit the reasons for such decision.

3. The requesting unit shall comply with the following conditions:

a. The requesting unit shall limit the dissemination of shared non-public information it receives to internal unit offices and/or employees that have been identified in its written request and/or have a need to know. The unit official who signs the request letter shall be responsible for ensuring that there are no inappropriate recipients of the information.

b. The requesting unit shall agree in writing, by using the model request letter (or a reasonable, mutually agreed upon facsimile), not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings. If the requesting unit wishes to disclose shared information that the sharing unit has designated as nonpublic, it shall first obtain the written permission of the sharing unit. If the requesting unit receives a Freedom of Information Act (FOIA) request for the shared information, it shall: (a) refer the request to the information-sharing unit for that unit to respond directly to the requester regarding the releaseability of the information, and (b) notify the requester of the referral and that a response will issue directly from the other unit.

c. The unit that shares non-public information shall include a transmittal letter along with any agency information shared. The transmittal letter shall indicate the type of information (e.g., confidential commercial information, personal privacy, or pre-decisional). A model transmittal letter is attached. The shared documents containing non-public information should be stamped ***"Do not disclose without permission of CBER/FDA or NIH/NINDS"*** as is applicable.

d. The requesting unit shall promptly notify the contact person or designee of the information-sharing unit when there is any attempt by a third party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

e. The requesting unit shall notify the information-sharing unit before complying with any judicial order that compels the release of shared non-public information, so that the units may determine the appropriate measures to take, including, where appropriate, the filing of a motion or an appeal with the court.

IV. NAME AND ADDRESS OF PARTICIPATING UNITS

A. Food and Drug Administration
Center for Biologics Evaluation and Research
29 Lincoln Drive (HFM-1)

Bethesda, MD 20892-4555
Telephone: (301) 827-0548
Fax: (301) 827-0440

B. National Institutes of Health
National Institute of Neurological Disorders and Stroke
Building 31, Room 8A52
31 Center Drive MSC 2450
Bethesda, MD 20892-2540
Telephone: (301) 496-3167
Fax: (301) 496-0296

V. LIAISON OFFICERS

Liaison Officers will participate in the management, coordination and oversight of this agreement and the attached Implementation Work Plan. The Liaison Officers will constitute a Steering Committee comprised of an equal number of member representatives from the FDA-CBER and the NIH-NINDS. Two Liaison Officers, one designate from each participating agency, will 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 mutual, written agreement by the signatories. The Liaison Officer Steering 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.

A. **A. For FDA/CBER**

Kimberly Benton, Ph.D.
Chief, Cell Therapy Branch
Division of Cell and Gene Therapy
Office of Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
US Food and Drug Administration
1401 Rockville Pike
WOC1 / Room 209N
Mail Code: HFM-720
Rockville, MD 20852
Telephone: (301) 827-5102
Fax: (301) 827-9796
E-Mail: BentonK@cber.fda.gov

Mercedes Serabian, M.S.
Chief, Pharmacology/Toxicology Review Branch
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
US Food and Drug Administration
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WOC1 / Room 223N
Mail Code: HFM-760
Bethesda, MD 20892
Telephone: (301) 827-6536
Fax: (301) 827-9796
E-mail: Serabian@cber.fda.gov

Donald W. Fink, Jr., Ph.D. (alternate)
Cell Therapy Review Branch
Division of Cell and Gene Therapy
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research
US Food and Drug Administration
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WOC1 / Room 201N
Mail Code: HFM-715
Bethesda, MD 20892
Telephone: (301) 827-5153
Fax: (301) 827-9796
E-mail: finkd@cber.fda.gov

B. For NIH/NINDS

Robert Finkelstein, Ph.D.
Director for Extramural Research
National Institute of Neurological Disorders and Stroke
National Institutes of Health
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Bethesda, MD. 20892
Telephone: (301) 496-9248
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Paul Scott, Ph.D.
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National Institutes of Health
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Email: ps199u@nih.gov

Robert Baughman, Ph.D. (alternate)
Associate Director for Technology Development
National Institute of Neurological Disorders and Stroke
National Institutes of Health
Neuroscience Center, 6001 Executive Blvd. Room 2137
Bethesda, MD. 20892
Telephone: (301) 496-1779
Fax: (301) 402-1501
Email: rb175y@nih.gov

VI. PERIOD OF AGREEMENT

This agreement becomes effective upon signature of both units and will continue for five years. It may be modified by mutual consent or terminated by either agency upon 120 days written notice. Not later than 120 days prior to the expiration of this agreement, each unit will provide a recommendation regarding the extension of the agreement, including modifications if any.

APPROVED AND ACCEPTED FOR NATIONAL INSTITUTES OF HEALTH
National Institute of Neurological Disorders and Stroke

By: Audrey Penn

Audrey Penn, M.D.
Acting Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health

Date: February 7, 2002

APPROVED AND ACCEPTED FOR THE THE FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research

By: Kathryn Zoon

Kathryn Zoon, Ph.D.
Center Director
Center for Biologics Evaluation and Research
Food and Drug Administration

Date: 02/12/02

ATTACHMENTS:
Model Request Letter
Model Transmittal Letter

APPENDIX: Implementation Work Plan

ATTACHMENTS

Model Language for Request from FDA/CBER

The Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) requests the following information from the National Institutes of Health, National Institute of Neurological Disorders and Stroke (NIH/NINDS) for the following purposes: ***[Identify information and purpose]***

FDA/CBER agrees that it will not disclose any information that NIH/NINDS shares with it and designates non-public without prior written permission from NIH/NINDS and that FDA/CBER will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA/CBER and NIH/NINDS dated ***[Insert date MOU between FDA/CBER and NIH/NINDS initiated]***. FDA/CBER acknowledges that applicable laws and regulations may govern the disclosure of such information. See, e.g., 5 U.S.C. § 552; 5 U.S.C. § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. Parts 20 and 21.

FDA/CBER will limit dissemination of any shared information to the following FDA/CBER offices and/or employees, unless it identifies additional FDA/CBER employees who have a need to know the non-public information: [Identify office(s) and/or employee(s)]

_____ _____
Name Date

[Signature and Date by FDA/CBER official with requisite responsibility and authority.]

Model Language for Request from NIH/NINDS

The National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/NINDS) requests the following information from the Food and Drug Administration/Center for Biologics Research and Review (FDA/CBER) that for the following purposes: ***[Identify information and purpose]***

NIH/NINDS agrees that it will not disclose any information that FDA/CBER shares with it and designates nonpublic without prior written permission from FDA/CBER and that NIH/NINDS will comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between NIH/NINDS and FDA/CBER dated _____. NIH/NINDS acknowledges that applicable laws and regulations may govern the disclosure of such information. See, e.g., 5 U.S.C. § 552; 5 U.S.C. § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. Parts 20 and 21.

NIH/NINDS will limit dissemination of any shared information to the following NIH/NINDS offices and/or employees, unless it identifies additional NIH/NINDS employees who have a need to know the non-public information: ***[Identify office(s) and/or employee(s)]***

_____ _____

Name Date

[Signature and Date by NIH/NINDS official with requisite responsibility and authority.]

Model Transmittal letter from NIH/NINDS to FDA/CBER

This letter accompanies information that the National Institutes of Health/National Institute for Neurological Disorders and Stroke (NIH/NINDS) is sharing with the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) in response to FDA/CBER's request, dated _____. This information contains one or more of the following categories of non-public information, including information the disclosure of which

may be prohibited by law:

[NIH/NINDS checks applicable numbers below]

__ confidential research proposals, progress reports, and/or unpublished data;
__ privileged or pre-decisional agency information;
__ trade secrets;
__ confidential commercial or financial information;
__ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;
__ information contained in records subject to the Privacy Act;
__ information contained in the inter-agency or intra-agency memoranda;
__ records or information compiled for law enforcement purposes;
__ information protected for national security reasons; or
__ other (explain).

FDA/CBER shall notify the contact person or designee of NIH/NINDS if there are any attempts to obtain such shared non-public information by compulsory process, including, but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA/CBER shall notify NIH/NINDS before complying with any judicial order that compels the release of such shared non-public information so that FDA/CBER and/or NIH/NINDS may take appropriate measures, including filing a motion with the court or an appeal.

By a signed request letter dated _____, FDA/CBER has agreed not to disclose the above-described shared non-public information without prior written permission of NIH/NINDS. FDA/CBER has acknowledged that applicable laws and regulations may govern the disclosure of such information. See, e.g., 5 U.S.C. § 552; 5 U.S.C. § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. Parts 20 and 21.

FDA/CBER has also agreed to comply with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA/CBER and NIH/NINDS, dated _____.

Model Transmittal letter from FDA/CBER to NIH/NINDS

This letter accompanies information that the Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER) is sharing with the National Institutes of

Health/National Institute for Neurological Disorders and Stroke (NIH/NINDS) in response to NIH/NINDS's request, dated _____. This information contains one or more of the following categories of non-public information, including information the disclosure of which may be prohibited by law:

[FDA/CBER checks applicable numbers below]

__ trade secrets;
__ confidential commercial or financial information;
__ information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
__ information contained in records subject to the Privacy Act;
__ information contained in inter-agency or intra-agency memoranda;
__ records or information compiled for law enforcement purposes;
__ information protected for national security reasons; or
__ other (explain).

NIH/NINDS shall notify the contact person or designee of FDA/CBER if there are any attempts to obtain such shared non-public information by compulsory process, including, but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

NIH/NINDS shall notify FDA/CBER before complying with any judicial order that compels the release of such shared non-public information, so that FDA/CBER and/or NIH/NINDS may take appropriate measures, including filing a motion with the court or an appeal.

By a signed request letter dated _____, NIH/NINDS has agreed not to disclose the above-described shared non-public information without prior written permission of FDA/CBER. NIH/NINDS has acknowledged that applicable laws and regulations may govern the disclosure of such information. See, e.g., 5 U.S.C. § 552; 5 U.S.C. § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j); 21 C.F.R. Parts 20 and 21. NIH/NINDS has also agreed to comply with the principles and procedures set forth in the Memorandum of Understanding on information between FDA/CBER and NIH/NINDS, dated _____.

APPENDIX

IMPLEMENTATION WORK PLAN FOR THE MEMORANDUM OF UNDERSTANDING BETWEEN THE FOOD AND DRUG ADMINISTRATION CENTER FOR BIOLOGICS EVALUATION AND RESEARCH AND THE NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

Introduction

The Food and Drug Administration/Center for Biologics Evaluation and Research (FDA/CBER), and the National Institutes of Health/National Institute of Neurological Disorders and Stroke (NIH/NINDS), have established a formal collaborative arrangement. The principal goal of this interagency working relationship is to expedite translation of basic research involving promising biological therapies to well-designed clinical studies for the treatment of neurological disorders and provide complementary support and expertise to enable each agency to better fulfill its public health mission.

This Implementation Work Plan itemizes specific projects and activities that constitute the substance of the collaborative arrangement between the two agencies, and is intended to serve as a general working plan for FDA/CBER and NIH/NINDS staff. Individuals designated by each agency to serve on interagency working groups will define the specific outcomes, completion timeframes, mechanisms of interaction, and other considerations associated with each project and activity. The relative priority of each project/activity is identified by the letters "I", for immediate (within 3 months), "S" for short-term (within 6-12 months), and "L" for long-term (beyond 12 months).

This agreement will be implemented on an incremental basis subject to 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 should be evaluated periodically to determine whether the benefits realized justify continuation or expansion of the activities conducted under this agreement. Success of this collaboration may lead to similar arrangements between other FDA and NIH units in the future.

The Working Group and the MOU will be supported in the budgets of both the FDA/CBER and NIH/NINDS in order to fund related activities, but are not expected to involve the exchange of funds. These activities will be planned in advance and budgets projected prior to the start of the fiscal year.

A. Information Exchange

- Initiate a series of introductory meetings and orientation briefings to acquaint FDA/CBER and NIH/NINDS personnel with each agency's statutory obligations, programs, operational capacities, policies, processes, etc. relevant to this agreement. [I]

- Identify key contact persons at each agency, and prepare a contact/referral directory to facilitate interagency communication and information exchange. [I]

- Establish a hyperlink between existing FDA/CBER and NIH/NINDS Internet websites to facilitate rapid access to routine and late-breaking information of mutual interest. [I]

- Establish an inter-agency forum for regular sharing of information related to new research initiatives by both agencies, investigational new drug and market applications for significant new products pending with FDA/CBER, emerging public health issues and emergencies, and policy development. Stem cells as cellular replacement therapies and gene transfer represent two specific examples that could serve as case studies to identify optimal working practices for both agencies to monitor an issue from the conceptual stage through research/development and clinical testing. [S]

- Use the inter-agency forum to share information on clinical research studies for treating neurologic disease that involve stem cells, gene transfer therapy and other therapeutic biologics such as recombinant proteins and monoclonal antibodies. Other information that may also be shared includes status updates on NIH/NINDS initiatives and funding of pre-clinical studies intended to promote development of novel biologic therapeutics for treating neurologic disorders, as well as advance notice of plans/agenda items for FDA/CBER committee meetings and workshops. [S]

- Assess the possibility of FDA/CBER and NIH/NINDS experts serving as Federal "facilitators" to oversee state-of-the-art advances in cellular and gene transfer technologies and therapeutics for treating neurological dysfunction through direct interactions with clinical investigators, product developers, scientific researchers, etc. One function of the facilitators would be to provide information on regulatory process and research funding to the commercial and academic research sectors, and to relay information on emerging products, in both the conceptual and development stage, back to NIH/NINDS and

FDA/CBER, with the goal of accelerating the flow of new, safe, and effective products from the research and development arena to the clinical environment. [L]

B. Education

- Staff jointly (by NIH/NINDS and FDA/CBER personnel) exhibitor's booths at national and international scientific or clinical meetings. This will enable FDA/CBER staff to interact directly with NIH/NINDS grantees in order to provide information about the regulatory review process to academic investigators, and to increase the visibility of FDA/CBER in the scientific community. [I]

- Present reciprocal in-house seminars to FDA/CBER and NIH/NINDS staff regarding the managed review regulatory process and the development of federally funded research initiatives and programs specifically applicable to the use of biologic therapies to treat neurological conditions and disorders. [S]

- Invite FDA/CBER staff to attend, participate in and/or present at NIH/NINDS-organized workshops and National Advisory Neurological Disorders and Stroke Council meetings, particularly when stem cells, gene transfer therapies or other related issues are under discussion. [S/L]

- Develop presentations on FDA/CBER requirements for conducting clinical trials involving fetal tissue and stem cell transplantation as well as gene transfer therapies to target investigators receiving NIH/NINDS funding. Topics to be covered would include the extent of proof-of-concept and pharmacological/toxicological pre-clinical testing expected with respect to determining target dosing and safety. Such presentations would be delivered at conferences such as the annual meetings of the American Academy of Neurology, the American Neurological Association, the Society for Neuroscience, the Congress of Neurological Surgeons, the American Society for Neural Transplantation and Repair, as well as the annual SBIR/STTR meeting, the bi-annual ASILOMAR International Symposium on Neural Regeneration, other stem cell meetings and relevant Gordon Research Conferences.

- Provide reference documents that describe the FDA/CBER investigational product and market approval processes for use by NIH/NINDS program staff and reviewers in conferring with prospective research grantees and contractors to help them plan their clinical studies to conform to FDA/CBER guidances and regulations where appropriate. Compliance with FDA/CBER requirements will eliminate duplication of effort, and streamline the process for academic clinical investigators seeking NIH/NINDS funding to conduct clinical studies that require an IND. [S/L]

- Review the feasibility and utility of live, jointly-produced video-teleconferences using FDA/CBER and/or NIH/NINDS facilities to communicate with each agency's constituencies on topical areas of interest, fast-moving events, new research and regulatory initiatives, etc. [S]

C. Resource Leveraging and Staff Collaborations

- Encourage collaborations between NIH/NINDS and FDA/CBER specialists; these could include rotations and service details of FDA/CBER scientists and clinicians in extramural and intramural divisions of NIH/NINDS, and of NIH/NINDS scientific staff and program directors in FDA/CBER regulatory offices. Such exchanges could promote a better understanding of the practices unique to each agency and enhance scientific exchange. [S]

- Provide the opportunity for FDA/CBER scientists and regulatory process experts to attend NIH/NINDS reviews of research applications, where they could provide valuable technical input to the reviewers. In turn, this at would enable FDA/CBER product reviewers to gain insight into future directions in research and product development, and to anticipate and prepare for scientific and clinical issues associated with future product applications. [S]

- Evaluate the feasibility of establishing a co-ordinated and efficient submission and review process for those clinical applications requesting NIH/NINDS funding and requiring submission of an IND to FDA/CBER. [S/L]

D. Policy Development

- Promote communication and consultation on select policy issues and guidance documents of particular interest and relevance to researchers, consumers and/or health care professionals that involve novel cellular or gene transfer therapies posing a potential health risk to the general public, or that relate to research and regulatory processes affecting the pace of translating research from bench-top to bed-side. For example, during drafting of policy documents such as FDA Guidance for Industry or NIH Points-to-Consider relating to cell or tissue-based therapy or gene transfer, each agency is encouraged to seek input from the other so that modifications can be made prior to the formal clearance process. [I]

E. Promotion of Interagency Joint Reviews

- Invite FDA/CBER input and recommendations during the development of NIH/NINDS-

initiated Requests for Applications (RFA) and Program Announcements (PA) that target relevant or essential research areas to foster and support the development of biologic tissue, cellular and gene transfer therapies for treating neurologic disease. [I]

- Provide for NIH/NINDS experts to participate in pre-decisional evaluation of selected relevant Investigative New Drug Applications seeking FDA/CBER authorization to conduct clinical studies involving novel biologic products whose scientific and clinical aspects may be complex or controversial. [S]

- Investigate the feasibility of allowing FDA/CBER staff with appropriate expertise to participate as members of the NIH/NINDS Stem Cell Working Group. FDA/CBER regulatory review scientists will see the types of grants funded by NIH/NINDS, and they could help identify important areas of research not being funded that would facilitate the development of biologic products for treating neurological disorders. [S/L]

- Create an opportunity for FDA/CBER medical officers with appropriate clinical training to serve as a consultant to the Clinical Trials Group at NIH/NINDS. [S/L]

- Provide advice on candidate nominations for appointment to FDA/CBER and NIH/NINDS review and planning bodies. [S/L]

F. Joint Sponsorship of State-of -Science Workshops/Conferences

- Provide for participation by FDA/CBER regulatory policy-makers and program officials in NIH/NINDS sponsored conferences that involve cell and gene transfer. Contributions from FDA/CBER may include: (1) participation in formal workshops, (2) individual presentations, (3) use of existing videotaped FDA teleconferences on selected regulatory policy and process issues, and technology transfer. In turn, NIH/NINDS staff will participate in FDA/CBER-sponsored workshops and conferences on relevant tissue, stem cell and gene transfer biologic therapies for treating neurologic dysfunction. Collaborative discussions and planning between NIH/NINDS and FDA/CBER could serve to focus the form and content of information and ensure appropriate coverage by both agencies at key extramural conferences and meetings. [I/S]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–3000]

Memorandum of Understanding Between the Food and Drug Administration and the Veterans Health Administration

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 Veterans Health Administration (VHA). The purpose of this MOU is to extend an existing formal collaboration between FDA and VHA for the purpose of developing and implementing terminology standards for medication information.

DATES: The agreement became effective June 28, 2005.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Health and Regulatory Data Standards (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411.

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: September 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S