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

225-05-3000

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

I. Background

The Veterans Health Administration (VHA) and the Food and Drug Administration (FDA) share a critical reliance on high quality, up-to-date medication information and information systems. Terminology is an essential infrastructure for information systems, and as a result medication terminology is "mission critical" for both agencies. For example, FDA has invested in the development and ongoing maintenance of the drug listing database, and is planning an electronic labeling system. VHA computer systems use medication terminology to safety-check and fill drug orders nationwide (57 million outpatient prescriptions yearly).

The missions of the FDA and VHA intersect in the area of medication knowledge. FDA collects, verifies, and distributes medication knowledge that benefits patients, providers, researchers, the private sector, and others worldwide. VHA uses FDA-generated medication knowledge for patient care, research, and education. In turn, VHA creates medication knowledge through well-established research and academic programs.

High quality medical terminology and other medication information contained in package inserts, is a shared and critical need for FDA and VHA. Fortunately, collaboration can increase terminology quality and reduce its costs. The agencies have begun to develop a history of informal and formal collaboration on terminology and drug information projects via collaboration on the FDA's electronic labeling project and VA's National Drug File Reference Terminology (NDFRT) project.

II. Purpose

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

III. Applicability

VHA and FDA will share information concerning terminology in medication information and will collaborate on projects related to this area including the electronic labeling information processing system, HL7 structured product labeling specification, and VHA NDFRT project.

IV. Scope of Work and Responsibilities

Based on common needs and a history of cooperation, this MOU establishes a formal mechanism for the Food and Drug Administration and VHA to collaborate on mutually beneficial terminology and drug information projects. Its scope includes collaboration in all

areas of terminology and knowledge management, such as terminology development, evaluation, implementation, and maintenance. The agreement anticipates that a variety of resources could be shared within the limits of applicable laws and regulations to benefit agency stakeholders. Examples of resources that could be shared under this agreement include human, facility and financial assets, contracting vehicles, software, and data.

V. Amendment of Agreement

This agreement shall become effective on the date both parties have signed their approval below. Any amendments and modifications as may be necessary shall be developed jointly between representatives of each department. Such amendments and modifications shall become effective by the signature approval of the parties signatory to the agreement or by their respective official successors.

VI. Duration of Agreement

This agreement becomes effective upon the signature of both parties and will remain in effect until September 30, 2006, unless extended by mutual consent of both parties. Either party, upon 60 days notice in writing, may accomplish termination of this agreement.

VII. Disputes

Disputes concerning the interpretation of this agreement shall be resolved by majority vote of a three-person dispute resolution committee. The committee shall consist of one VA representative, one Food and Drug Administration representative and one neutral representative agreed upon by both VA and FDA.

VIII. Project Officers

For VHA:

Steven H. Brown M.D
Director, CPEP and
Enterprise Architecture Group, VA Office of Information
1310 24th Avenue South
Nashville, TN 37212
Tel: 615-321-6335

For FDA:

Randy Levin MD
Director for Health and Regulatory Data Standards
Food and Drug Administration
Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
Tel: 301-594-5411

IX. Acceptance By Both Parties To The Agreement

FOR THE DEPARTMENT OF VETERANS AFFAIRS, VHA	FOR HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
By (Signature) Robert M Kolodner	By (Signature) Janet Woodcock MD
Name Robert M. Kolodner, M.D.	Name
Title Acting VHA Chief Health Informatics Officer	Title Acting Deputy Commissioner for Operations
Date 6/13/2005	Date 6/28/05

[FR Doc. 05–18513 Filed 9–16–05; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0340]

Draft Guidance for Industry on Acne Vulgaris: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Acne Vulgaris: Developing Drugs for Treatment.'' This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne.

DATES: Submit written or electronic comments on the draft guidance by December 19, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frank Cross, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acne Vulgaris: Developing Drugs for Treatment.'' This document has been developed to provide guidance on the development of drug products for the treatment of acne vulgaris other than nodulocystic acne. The information presented may help applicants plan clinical studies, design clinical protocols, implement and appropriately monitor the conduct of clinical trials, collect relevant data for analysis, and perform appropriate types of analyses of study data.

The recommendations in the draft guidance are based on careful assessment of important issues raised in the review of clinical trials for acne vulgaris. These recommendations represent the agency's current thinking regarding design of clinical trials intended to support the approval of drug products for the treatment of acne vulgaris. Applicants are encouraged to discuss development plans with the agency review division before embarking on a study, to ensure that the