TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of Standard	Reference No. and Date
10–57	Phakic Intraocular Lenses	ANSI Z80.13–2007
I. Physical Medicine		
16–161	Safety Standard for Platform Lifts and Stairway Chairlifts	ASME A18.1–2005
J. Sterility		
14–255	Standard Terminology Relating to Flexible Barrier Packaging	ASTM F17–07a

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

Persons interested in obtaining a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions [including lists of approved applications and manufacturers' addresses], small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 020. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: August 27, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–20939 Filed 9–8–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–08–8001]

Memorandum of Understanding Between the Food and Drug Administration and the University of Pennsylvania

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 University of Pennsylvania (Penn). The purpose of this MOU is to establish terms of collaboration between FDA and Penn focused primarily but not exclusively, in the areas of translational therapeutics, diagnostics, bioinformatics, new clinical trial models, drug/device co-development, and pharmacoepidemiology. Beyond the collaborations in the traditional academic programs for training, research, and outreach, this MOU will also include collaborations with Penn extended partnerships such as the Institute for Translational Medicine and Therapeutics which includes the Children's Hospital of Philadelphia, the Wistar Institute, and the University of Sciences in Philadelphia.

DATES: The agreement became effective on July 24, 2008.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Office of the Commissioner, Office of Scientific and Medical Programs (HF–18), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7867.

For Penn: Glenn N. Gaulton, PENN Medicine, University of Pennsylvania, 421 Curie Blvd., Philadelphia, PA 19104–6160, 215–898–2874.

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 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

BILLING CODE 4160–01–S

FDA Record No. 225-08-8001

Memorandum of Understanding

Between
The United States Food and Drug Administration
And
The University of Pennsylvania

This Memorandum of Understanding (MOU) between the U.S. Food and Drug Administration (FDA) and the University of Pennsylvania (Penn) (FDA or Penn, individually, "Party" and collectively "Parties") is established to formalize the development of collaborative activities between the two parties in the areas of research, education, and outreach. This MOU describes in general terms the basis upon which the parties intend to cooperate in these activities. The MOU does not create binding, enforceable obligations against, or in favor of, either party.

I. Purpose

The purpose of this MOU is to establish the framework for collaboration between FDA and Penn to support their shared interest in advancing the scientific basis for the regulatory approval process and medical product development through: (1) the promotion of a sound working relationship between the FDA and Penn; (2) the exchange of graduate and undergraduate students, faculty, and personnel; and (3) cooperative activities, sponsored research activities, and information exchange in areas such as translational therapeutics, diagnostics, bioinformatics, the development of new clinical trial models, drug/device co-development, and innovative drug therapy-monitoring programs.

The specific goals of the collaboration which are expected to result from this MOU are to advance: (1) the utilization of new technological tools to hasten development of safer, more useful drugs, biologics and medical devices (collectively, "medical products") targeted at individuals rather than populations; (2) the utilization of pharmacoepidemiology to monitor the efficacy, safety and cost-effectiveness of medical products subsequent to their marketing (3) the understanding of co-development processes for companion drug diagnostics for targeted therapies; (4) the entry of new medical products into the marketplace at reduced cost without compromising safety or efficacy; and (5) the quality and quantity of professionals trained in the emerging field of translational medicine and therapeutics.

II. Background

FDA has a primary role in assuring the safety and efficacy of newly approved medical products. In addition, FDA plays a unique role in advancing the translational/applied science that assists US industry and academia in streamlining the medical product development process.

Penn has established an Institute for Translational Medicine and Therapeutics (ITMAT), as a chartered non-profit research and education center. ITMAT is dedicated to research at the interface of basic and clinical science, with a particular focus on the development of new and safer medical products. ITMAT includes its own faculty and investigators focused on clinical and translational research in all schools at Penn, the Children's Hospital of Philadelphia (CHOP), the Wistar Institute, and the University of Sciences in Philadelphia. Examples of key research areas of the ITMAT include neurotherapeutics, systems biology and targeted therapeutics.

III. Agreement

This MOU is intended as a broad vehicle to promote collaboration between FDA and Penn researchers, students, and personnel. As specific topics for joint research and/or collaboration are identified under this MOU they will be conducted under the appropriate formal agreements.

The areas of collaboration will include, but will not be limited to, the following:

A) Translational Therapeutics (the branch of medical research that fosters the connection between basic research and patient care).

At least two areas of collaboration between FDA and Penn relative to translational therapeutics have been identified:

1) Joint research that moves the study of pharmacology from model systems to humans for rational dose selection and safe delivery of medical products, including the integration of hypothesis driven and unbiased science-based approaches to foster individual medical product selection and risk management.

2) Regular workshops and conferences to integrate translational therapeutics and pharmacoepidemiology to predict and refine strategies for monitoring approved medical products in the postmarketing phase to ensure safety.

B) Biomarkers

Several areas of potential collaboration between FDA and Penn relative to biomarkers and new tools in bioinformatics have been identified, including:

1) Joint research programs may be formed by scientists from their respective institutions with mutual complementary interests in areas such as the study of environmental and

genetic factors that contribute to variation in human responses to medical products. This research may be based on collaborative analysis of data and the literature, or experimental work. The partners will disseminate information and enhance the visibility of the collaboration through mutually agreed vehicles, including training activities, meetings, symposia and journal publications.

2) Joint participation and / or sponsorship of conferences on issues related to inter-individual differences in the response to medical products, and the need to develop new approaches to clinical trial design and analysis.

C) Pharmacoepidemiology

FDA and Penn will work collaboratively to develop a medical product therapy-monitoring program assessing utilization, clinical effectiveness, safety, and prescription guideline adherence.

D) Curriculum Development and Training

The growing complexity of medical product discovery, development, approval and regulation requires individuals cross-trained in the new interdisciplinary biomedical science of translational therapeutics, requiring the evaluation of data derived from studies in molecular pharmacology, pharmacogenomics, medical informatics, pharmaceutics, clinical pharmacology, and pharmacoepidemiology, among others. There is a significant shortage of individuals cross-trained in these fields and available for employment by the FDA, academia or industry. Working collaboratively, FDA and Penn propose to develop a translational therapeutics curriculum, building upon the ITMAT's Masters in Translational Research (MTR) degree program. The goal of this effort will be to develop the capacity to create satellite activities at other academic medical centers throughout the United States, to train credentialed experts in the emerging field of translational medicine and therapeutics and clinical pharmacoepidemiology.

IV. General Provisions

Nothing in this MOU alters the statutory authorities or obligations of FDA. This MOU is intended to facilitate the cooperative efforts of the Parties. The MOU does not create binding, enforceable obligations against, or in favor of, either party.

1) Information Sharing: Proprietary or non-public information will not be disclosed under this MOU unless such disclosure is governed by appropriate, separate, written Confidentiality Disclosure Agreements ("CDAs") and to the extent such disclosure is permitted by Federal law.

2) Conflict of Interest: Participants from the parties will abide by the conflict of interest policies and rules of their respective institutions (i.e., participants from Penn will need to abide by Penn's conflict of interest policies and rules and

participants from FDA need to abide by Office of Government Ethics' Standards of Ethical Conduct for Employees of the Executive Branch, and FDA's conflict of interest policies and rules)

V. Resource Obligations

Execution of this MOU will not result in the obligation of federal funds, personnel, or other resources by FDA. Nothing in this Agreement shall obligate HHS, or FDA to any current or future expenditure of resources in advance of the availability of appropriations from Congress.

VI. Term, Termination and Modifications

1) This MOU constitutes the entire agreement between the Parties as to the matters described herein, and there are no representations, warranties, agreements, or understandings, expressed or implied, written or oral, between the Parties relating to the subject matter of this MOU that are not fully expressed herein.

2) This MOU may be modified only upon the mutual written consent of both Parties. Modifications must be signed by the original signatories to this MOU, or by their designees or successors. No oral statement by any person shall be interpreted as modifying or otherwise affecting the terms of this MOU.

3) This MOU, when accepted by the Parties, will remain in effect for five (5) years from the effective date, unless modified or terminated. This MOU will become effective on the date of the last signatory to the agreement.

4) This MOU may be terminated by written notice by either of the Parties at any time, with or without cause, and without incurring any liability or obligation to the terminated Party, by giving the other party at least thirty (30) days prior written notice of termination.

5) Any notice or other communication required or permitted under this MOU shall be in writing and shall be deemed effective on the date it is received by the receiving Party.

6) This agreement shall be governed by applicable federal law.

7) This MOU shall be publicly available.

VII. Name and Address of Participating Parties

A. Penn
University of Pennsylvania
3451 Walnut Street Philadelphia, PA 19104

B. FDA
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

VIII. Liaison Officers

A. For FDA

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B. For Penn

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Email: gaulton@mail.med.upenn.edu
Phone: 215-898-2874
Fax: 215- 573-7945

FDA Record No. 225-08-8001

AGREED TO:

FOR THE UNIVERSITY OF PENNSYLVANIA

BY: _____ 7/18/08
Signature of authorized representative **Date**

Arthur H. Rubenstein, M.B.B.Ch.
Executive Vice President
University of Pennsylvania for the Health System
Dean
School of Medicine

FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION

BY: _____ 7/24/08
Signature of authorized representative **Date**

Frank M. Torti, M.D., MPH
Chief Scientist and Deputy Commissioner
Food and Drug Administration

[FR Doc. E8–20932 Filed 9–8–08; 8:45 am]
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