pharmaceuticals and related products. The goal of the conference is to ensure widespread opportunities for attendees to learn about important and critical issues that intersect with pharmaceutical manufacturing quality and regulatory topics that impact manufacturers, suppliers, and regulatory health authorities.

II. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of conference sessions and presentations, facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.ispe.org/2015-quality-manufacturing-conference/fees-and-registration.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
ISPE Members	$2,095
Nonmembers	2,475
Government	700

III. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at The Mayflower Renaissance, Washington DC, may check for the availability of a reduced rate by mentioning ISPE when making their reservation.

Dated: May 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11620 Filed 5–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1349]

Electronic Study Data Submission; Data Standards; Support for the Logical Observation Identifiers Names and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is encouraging sponsors and applicants to provide Logical Observation Identifiers Names and Codes (LOINC) codes (available at *http://loinc.org/*) for clinical laboratory test results in investigational study data provided in regulatory submissions submitted to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. LOINC code is defined as electronic messages for laboratory test results and clinical observations. The decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives. FDA invites public comment on appropriate steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. The LOINC common terminology will be listed in the FDA Data Standards Catalog that is posted to FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments by June 29, 2015.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–002, 301–796–5333, *ronald.fitzmartin@fda.hhs.gov*, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

LOINC is a clinical terminology housed by the Regenstrief Institute, a nonprofit medical research organization associated with Indiana University (available at *http://www.regenstrief.org/*). LOINC was initiated in 1994 as a response to the demand for electronic movement of clinical data from laboratories that produce the data to consumers of clinical data. LOINC codes are universal identifiers for laboratory and other clinical observations that enable semantically interoperable clinical data exchange. The purpose of LOINC is to facilitate the exchange and pooling of clinical data for clinical care, outcomes management, and research.

The laboratory portion of the LOINC database contains the categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, and more. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, and selected survey instruments.

FDA is now encouraging sponsors and applicants to provide LOINC codes for laboratory test data in investigational studies provided in regulatory submissions (*e.g.,* investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs)) when those LOINC codes are available (*e.g.,* from the clinical laboratory that performed the test). FDA supports LOINC-coded laboratory test results because: (1) LOINC is widely used among clinical laboratories, (2) LOINC-coded lab data make the information easier to understand and analyze, and (3) the currently supported exchange standard for laboratory test results in clinical trials, the Study Data Tabulation Model (available at *http://www.cdisc.org/sdtm)* already supports the exchange of LOINC codes. FDA's decision to adopt LOINC for lab test results is part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives.

FDA recognizes that there are additional steps the Agency could take to promote the use and utility of LOINC-coded clinical data submitted to the Agency. FDA invites public comment on what those additional steps should be, along with a suggested sequence and timing of those steps. For example, the Agency recognizes that the high level of granularity inherent in LOINC has

presented coding challenges and that these challenges have led to the creation of subsets of LOINC to help facilitate coding.

- Should FDA identify a LOINC subset for its use case?
- If yes, should FDA create its own subset or leverage existing subsets?
- Which LOINC subsets should FDA consider?
- What steps can FDA take to minimize the burden to sponsors and applicants in adopting LOINC within their organizations to support regulatory submissions?

II. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this notice to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: May 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11596 Filed 5–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0509]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Dispute Resolution Procedures for Science Based Decisions on Products Regulated by the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Dispute Resolution Procedures for Science Based Decisions on Products Regulated by the Center for Veterinary Medicine'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On February 18, 2015, the Agency submitted a proposed collection of information entitled, ''Dispute Resolution Procedures for Science Based Decisions on Products Regulated by the Center for Veterinary Medicine'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0566. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11608 Filed 5–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1491]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey of Pharmacists and Patients; Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 15, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Survey of Pharmacists and Patients; Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Pharmacists and Patients; Variations in the Physical Characteristics of Generic Drug Pills and Patients' Perceptions (OMB Control No. 0910—NEW)

Generic drugs make up approximately 85 percent of all human prescription drugs prescribed in the United States. While generic drugs are required to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts, generics made by different manufacturers may differ substantially from their brand-name therapeutic equivalents and from each other in their physical appearance (*e.g.,* color, shape, or size of pills). When pharmacists switch generic drug suppliers, patients refilling their generic prescriptions may therefore experience changes in their drugs' appearances. These changes may result in patient confusion and concerns about the safety and effectiveness of the generic drug products. Studies indicate that patients are more likely to stop taking their generic medications when they experience a change in their drugs' physical appearances, leading to harmful clinical and public health consequences as well as increased health care costs from avoidable morbidity and mortality.

To provide additional information that may help guide regulatory policy or pharmacy business practices, we intend to conduct surveys of pharmacists and patients about their perceptions about and experiences with generic drug product pill appearance change. These surveys are intended to further our understanding of the relationship between changes in pill appearance and non-adherence to prescribed therapeutic regimens. The surveys may enable us to investigate factors that may explain the association between changes in pill