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

appearance and non-adherence, including which factors could be modified to improve the safe and effective use of generic drugs.

We intend to survey a national cohort of pharmacists about their experiences with dispensing generic drug pills that differ in appearance from previous refills of the same medication and dosage level (*e.g.,* when pharmacies switch generic suppliers). A stratified, random sample of U.S.-licensed pharmacists will be obtained based on a master list from KM Lists. The target sample includes pharmacists with active licenses who practice in traditional community pharmacy settings and will be proportionally allocated across the U.S. in relation to the number of pharmacists in each state. Based on an 11 percent undeliverable rate and a 52 percent response rate, 2,161 questionnaires will be mailed to pharmacists to obtain the 1,000 responses required for adequate statistical power. The pharmacists' survey will consist of a mailed questionnaire rather than a telephone survey or an email survey. Prior experience conducting surveys has shown that it is easier to guarantee respondent anonymity using an impersonal, mailed questionnaire with no individual identifying information. The pharmacists will be asked about the frequency with which their pharmacy changes suppliers that lead to variations in the appearance of the generic drugs that they dispense, as well as strategies they use with patients to address the transition to pills that have a different appearance (*e.g.,* alert stickers on pill bottles, verbal warnings, and other strategies). They will also be asked about patient responses to changes in pill appearance, including what types of appearance changes seem to affect patients most often (shape/color/size), how often patients report confusion about pill appearance, and how often patients ultimately refuse to accept the new product. Participation is expected to take approximately 20 minutes.

We also intend to survey two different patient samples using two methodologies. The first is a telephone survey of patients who are 50 years and older and who take one or more generic medications for at least one of the following chronic conditions: Epilepsy, diabetes, hypertension, hyperlipidemia, depression, and HIV. The telephone survey will be generalizable and will consist of well-defined methods to minimize sampling bias such as use of random phone numbers for both landlines and mobile phones, as well as small-batch sampling to ensure a high response rate that meets demographic diversity goals. For the second patient survey, patients will be selected from a proprietary research database of commercially insured patients containing medical and pharmacy claims linked to health insurance enrollment information. A nationally representative sample of patients with at least one chronic condition and who experienced a change in physical appearance of a generic pill will be identified by the research team using medical and pharmacy claims data. Both patient surveys will consist of questions covering topics similar to those asked in the survey of pharmacists and is intended to provide answers to the same topic areas from patients' perspectives. As before, topic areas will include beliefs about generic drugs, outcomes related to changes in generic drug pill appearance, and strategies used by pharmacists or doctors to alert patients to the possibility of changes in appearance. Participation is expected to take approximately 20 minutes.

In the **Federal Register** of October 15, 2014 (79 FR 61872), FDA published a 60-day notice requesting public comment on the proposed collection of information. Comments submitted raised several issues pertaining to the proposed collection of information. We summarize the comments and provide our responses below:

(Comment 1) Two comments expressed concerns related to trade dress protection issues, noting that the requirement that generic products differ in appearance from the Reference Listed Drug is well established in case law. A pill's physical appearance can qualify as trade dress, protected under the Lanham Act (Pub. L. 79–489), which functions to distinguish between products from different manufacturers. A drug's physical appearance can also be considered a protected form of non-verbal expression under the First Amendment. If required to change the appearance of their medications, the generic industry would face additional development costs.

(Response) The purpose of these surveys is to gather information on the awareness of patients and pharmacists about changes in the appearance of medications, the frequency with which changes in appearance occurs, strategies that pharmacists use to inform patients when the appearance of their medications changes, and the outcomes associated with these strategies. The results of the surveys will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes. The purpose of these surveys is not to reverse existing legal precedents, require the generic drug industry change the appearance of their medications, or support the infringement of intellectual property, First Amendment, or any other legally protected interests.

(Comment 2) One comment mentioned that the term ''pill'' is used in the **Federal Register** notice to describe oral solid dosage forms such as tablets and capsules, but is defined by Merriam-Webster much more narrowly to exclude tablets and capsules, which has the potential to create confusion.

(Response) Because the FR notice is seeking opinions from the public, we used language accessible to the general public. To avoid confusion, the word ''pill'' is defined in the introduction of each survey instrument to clarify its meaning, with the statement that the word ''pill'' includes both tablet and capsule dosage forms.

(Comment 3) One comment mentioned that the survey findings may be used by FDA to guide pharmacy business practice, which is the jurisdiction of the State Boards of Pharmacy.

(Response) As stated earlier, the purpose of these surveys is to gather information on the awareness of patients about changes in the appearance of their medications, the frequency with which changes in appearance occurs, strategies that pharmacists use to inform patients when the appearance of their medications changes, and the outcomes associated with these strategies. The results of the surveys will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes. FDA does not intend to, itself, guide pharmacy business practices.

(Comment 4) One comment expressed concern that confidential patient information from an insurance database will be identified and shared with Federal Government employees, which may violate HIPAA regulations.

(Response) These surveys received approval from the Institutional Review Board (IRB) at the academic medical center where the survey is being conducted, which was accepted by FDA's IRB (Research In Human Subject Committee). IRB approval ensures compliance with human subjects' protection laws, including HIPAA. No FDA personnel will have access to any identifiable patient information.

(Comment 5) One comment suggested that instead of conducting the study, FDA should data mine an internal source of data (product complaints received from pharmaceutical companies, healthcare providers, and consumers) to gather information on potential confusion and medication mistakes.

(Response) The proposed study focuses on patient and pharmacist experiences and outcomes associated with changes in pill appearance, a topic of which patient confusion and medication mistakes are only a part. Although some medication mistakes and patient confusion data may be captured in our internal database (FDA's Adverse Event Reporting System), the specific data sought from the proposed study do not exist in this database.

(Comment 6) One comment suggested that if the information on potential confusion and medication mistakes cannot be found in current databases, FDA should request that pharmacy school students conduct this study and publish results in a peer-reviewed journal to assure transparency and reduce government spending.

(Response) High-quality surveys require substantial resources that would likely not be available to pharmacy students for class projects. These surveys are being conducted by an academic medical institution that has expertise in conducting surveys of patients and health care providers, which will provide high-quality and valid data and assure transparency. The results will be published in a peer-reviewed journal(s) and will be made publicly available.

(Comment 7) One comment mentioned that these surveys will collect data on pharmacist and patient perceptions, which may not correlate to actual use data and thus may not provide meaningful information on safe and effective use of generic drugs or yield substantial evidence to support adoption of any regulatory policies. The comment noted that further investigations will be needed to understand how pharmacist and patient perceptions translate to actual practices and effects, and encouraged FDA to consider comments to Docket No. 2013–N–1434 in considering what further work will be needed and the level of evidence needed to support any regulatory policy changes.

(Response) These surveys include questions on patient and pharmacist perceptions, as well as their actual experiences and behaviors as they relate to generic drugs and changes in drug appearance. The survey findings will be used to inform the development of patient education about differences in pill appearance and inform the development of education for pharmacists on strategies to counsel patients when the appearance of their medications changes.

(Comment 8) One comment noted that if this study is conducted, the surveys should be carefully crafted to collect useful data using validated, well-developed methodology and assumptions. The comment requested the opportunity to review the proposed surveys and to submit additional survey questions.

(Response) Well-established survey methods are being used in the development and conducting of this survey. The survey questions were carefully crafted according to published guidelines for survey question development (Refs. 1 & 2) and were further refined by an expert panel that included individuals with pharmacy-related professional backgrounds and patient representatives. The survey instruments will undergo cognitive testing and formal pre-testing to ensure questions are clear and answerable, and that study results are valid and useful. A copy of the draft surveys have been provided to the commenter.

(Comment 9) One comment noted that the variations in the physical appearance of drug products may help pharmacists and patients avoid confusion, facilitate detection of counterfeit drug products, and serve pharmacovigilance purposes by providing information about the source of a specific product. Variation in pill appearance can also serve to notify patients that the source of their medication has changed. FDA should acknowledge the ways in which differences in pill appearance are beneficial when determining whether and how to conduct the survey.

(Response) The focus of these surveys is on identifying patient and pharmacist concerns and problems related to changes in pill appearance, with the goal of informing the development of future patient and provider educational interventions and programs to address identified problems. However, it is acknowledged that changes in the physical appearance of medications could have both negative and beneficial effects. Therefore, questions have been added to gauge how changes in pill appearance may benefit pharmacists and patients.

(Comment 10) One comment commended FDA for planning this study. The commenter was also pleased that FDA plans to conduct two separate patient surveys to ensure that a broad and relevant patient experience is reflected in the results.

(Response) We thank this commenter for the support of our study and agree that conducting two separate patient surveys will improve the validity and generalizability of the results.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1]

Surveys of pharmacists and patients on variations in the physical characteristics of generic drug pills and patients' perceptions	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
Pharmacist surveys mailed [2]	2,161				
Pharmacist pretests	9	1	9	0.333 (20 minutes)	3
Pharmacist survey completes	1,000	1	1,000	0.3 (18 minutes)	300
Patient #1 survey calls	5,000				
Patient #1 surveys screened	3,330	1	3,330	0.033 (2 minutes)	111
Patient #1 surveys eligible	1,200				
Patient #1 survey pretests	9	1	9	0.333 (20 minutes)	3
Patient #1 survey completes	1,000	1	1,000	0.3 (18 minutes)	300
Patient #2 surveys mailed [2]	2,000				

TABLE 1—ESTIMATED REPORTING BURDEN [1]—Continued

Surveys of pharmacists and patients on variations in the physical characteristics of generic drug pills and patients' perceptions	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total Hours
Survey of patients #2	1,000	1	1,000	0.3 (18 minutes)	300
Total					1,017

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Eligibility is determined prior to mailing the surveys; screening is not required.

References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Woodward, C.A., ''Questionnaire Construction and Question Writing for Research in Medical Education,'' *Medical Education,* 22, pp. 345–363 (1988).
2. Fitzpatrick, R., ''Surveys of Patient Satisfaction: II—Designing a Questionnaire and Conducting a Survey,'' *British Medical Journal,* 302(6785), pp. 1129–1132 (1991).

Dated: May 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11623 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–1031]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; FDA Recall Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''FDA Recall Regulations'' 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 27, 2015, the Agency submitted a proposed collection of information entitled, ''FDA Recall Regulations'' 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 0910–0249. The approval expires on March 31, 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 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11624 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–1076]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry: Formal Dispute Resolution; Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Guidance for Industry: Formal Dispute Resolution; Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice'' 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 January 8, 2015, the Agency submitted a proposed collection of information entitled, ''Guidance for Industry: Formal Dispute Resolution; Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice'' 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 0910–0563. 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 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11609 Filed 5–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2015–0020]

The U.S. Customs and Border Protection Airport and Seaport Inspections User Fee Advisory Committee (UFAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Public Committee Meeting.

SUMMARY: The U.S. Customs and Border Protection Airport and Seaport Inspections User Fee Advisory Committee (UFAC) will meet on Tuesday, June 2, 2015, in Washington,