

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]

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## 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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.*

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## 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 [aira\\_submission@omb.eop.gov](mailto:aira_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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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