that are performing waived testing in addition to moderate or high complexity testing will need to meet all requirements in subpart K, Quality System for Nonwaived Testing. The A2LA has more specific requirements for laboratory information systems than CLIA. In addition, prior to adding a new test to the laboratory's accreditation, the A2LA requires the laboratory to submit performance specifications for review and approval.

E. Subpart M—Personnel for Nonwaived Testing

We have determined that the A2LA's requirements are equal to or more stringent than the CLIA requirements at § 493.1403 through § 493.1495 for laboratories that perform moderate and high complexity testing. Under the A2LA's requirements, laboratories that perform moderate complexity testing must meet the personnel requirements for high complexity testing located at § 493.1441 through § 493.1495.

F. Subpart Q—Inspections

We have determined that the A2LA requirements for the submitted subspecialties and specialties are equal to or more stringent than the CLIA requirements at § 493.1771 through § 493.1780. The A2LA requires a two day onsite surveillance visit one year after the initial accreditation is granted. The A2LA requires annual review of all accredited laboratories. The laboratory is required to submit any updates on information about its organization, facilities, key personnel and results of any proficiency testing. Laboratories may be required to undergo an onsite surveillance visit if they do not submit their annual review documentation to the A2LA by the established 30 day deadline, if significant changes to the facility or organization have occurred, or if proficiency testing results have been consistently poor. The CLIA regulations do not have this requirement.

G. Subpart R—Enforcement Procedures

The A2LA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The A2LA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the A2LA will deny, suspend, or revoke accreditation in a laboratory accredited by the A2LA and report that action to us within 30 days. The A2LA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the A2LA's laboratory enforcement and appeal policies are equal to the requirements of part 493, subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the A2LA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the A2LA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the A2LA, for cause, before the end of the effective date of approval. If we determine that the A2LA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the A2LA would be allowed to address any identified issues. Should the A2LA be unable to address the identified issues within that timeframe, we may, in accordance with the applicable regulations, revoke A2LA's deeming authority under CLIA.

Should circumstances result in our withdrawal of the A2LA's approval, we will publish a notice in the **Federal Register** explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: March 14, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–06512 Filed 3–24–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0250]

Draft Guidance for Industry on Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway; 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 ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' This draft guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under the accelerated approval regulatory pathway (hereafter ''accelerated approval''). The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 27, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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: Ann Marie Trentacosti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6485, Silver Spring, MD 20993–0002, 301–796–2901; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products Approved Under the Accelerated Approval Regulatory Pathway.'' Labeling must conform to the content and format requirements delineated in §§ 201.56(d) and 201.57 (21 CFR 201.56(d) and 201.57). Special provisions exist for older drug labeling under §§ 201.56(e) and 201.80. Labeling for drugs approved under the accelerated approval process is fundamentally the same as for drugs approved under the traditional pathway; however, for drugs approved under accelerated approval there are additional labeling requirements as described in § 201.57(c)(2)(i)(B) and recommended elements for consideration.

This draft guidance discusses FDA's recommendations for developing the indication and usage statements in the prescribing information for drugs approved under accelerated approval as defined in 21 CFR part 314, subpart H (for new drug applications) and 21 CFR part 601, subpart E (for biologics license applications) when the approval is based on an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The guidance also discusses labeling considerations for indications approved under accelerated approval when clinical benefit has been verified and FDA terminates the conditions of accelerated approval under 21 CFR 314.560 or 21 CFR 601.46, or when FDA withdraws accelerated approval of an indication while other indications for the drug remain approved.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on labeling for human prescription drug and biologic products approved under accelerated approval. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments 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*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/biologicsbloodVaccines/GuidanceComplianceRegulatoryInformation/guidances/default.htm,* or *http://www.regulations.gov*.

Dated: March 19, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–06471 Filed 3–24–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The Hispanic Community Health Study/Study of Latinos (HCHS/SOL)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung and Blood Institute (NHLBI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Larissa Aviles-Santa, 6701 Rockledge, Epidemiology Branch, Program in Prevention and Population Sciences, Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., MSC 7936, Bethesda, MD 20892–7936, or call non-toll-free number 301–435–0450, or Email your request, including your address to *avilessantal@nhlbi.nih.gov*. Formal requests for additional plans and