Assistance Programs (SHIPs), Area Agencies on Aging (AAAs), and Aging and Disability Resource Center programs (ADRCs), to inform Medicare beneficiaries about available Federal and State benefits. ACL seeks plans from states that will describe how the MIPPA funds will be used for beneficiary outreach and education over the next two years.

ACL requests that states submit a two year state plan with specific project strategies to expand, extend, or enhance the outreach efforts to beneficiaries on Medicare Part D and for those with limited incomes. States should describe how the SHIP, AAA, and ADRC efforts will be coordinated to provide outreach to beneficiaries with limited incomes statewide, for general Medicare Part D outreach and assistance to beneficiaries in rural areas, and for outreach activities aimed at Medicare prevention and wellness benefits as well as the improvements in the Part D program under the Affordable Care Act as mandated by Section 3306 of the Act. States that are eligible to apply are asked to review previous MIPPA plans and update these plans to reflect successes achieved to date and direct their efforts to enhance and expand their MIPPA outreach activities. State agencies may prepare either one statewide plan or separate plans for each eligible State agency.

II. Award Information

1. Funding Instrument Type

These awards will be made in the form of grants to State Agencies for each MIPPA Priority Area.

Priority Area 1—Grants to State Agencies (the State Unit on Aging or the State Department of Insurance) that administer the State Health Insurance Assistance Programs to provide enhanced outreach to eligible Medicare beneficiaries regarding their benefits and enhanced outreach to individuals who may be eligible for the LIS or for the MSP.

Priority Area 2—Grants to State Units on Aging for AAAs to provide enhanced outreach to eligible Medicare beneficiaries regarding their benefits and enhanced outreach to individuals who may be eligible for the LIS, MSP, Medicare Part D and Part D in rural areas.

Priority Area 3—Grants to State Units on Aging that administer the Aging and Disability Resource Centers to provide outreach to individuals regarding the benefits available under Medicare Part D and under the MSP. Funds will be allocated to ADRCs via a formula patterned after the statutory formula used for SHIPs and AAAs.

2. Anticipated Total Priority Area Funding per Budget Period

ACL intends to make available, under this program announcement, grant awards for the three MIPPA priority areas. Funding will be distributed through a formula as identified in statute. The amounts allocated are based upon factors defined in statute and will be distributed to each priority area based on the formula. ACL will fund total project periods of up to two (2) years contingent upon availability of federal funds.

Priority Area 1—SHIP: $7.5 million in FY 15 and potentially $13 million in FY 16 for state agencies that administer the SHIP Program.

Priority Area 2—AAA: $7.5 million in FY 15 and potentially $7.5 million in FY 16 for SUAs for Area Agencies on Aging and for Native American programs. Funding for Native American Programs ($264,000) is deducted from Priority 2 and is being allocated through a separate process.

Priority Area 3—ADRC: $5 million in FY 2015 and potentially $5 million in FY 16 for state agencies that administer ADRC programs that were established prior to March 2014.

III. Eligibility Criteria and Other Requirements

1. Eligible Applicants MIPPA Priority Areas 1, 2 and 3

Awards made under this announcement, by statute, will be made only to agencies of State Governments.

Priority Area 1: Only existing SHIP grant recipients are eligible to apply.

Priority Area 2: Only State Units on Aging are eligible to apply.

Priority Area 3: Only State Agencies that received an ACL and CMS Aging and Disability Resource Center (ADRC) grant where the ADRC was established by March, 2015 are eligible in FY 2015.

Eligibility may change if future funding is available.

2. Cost Sharing or Matching Is Not Required.

3. DUNS Number

All grant applicants must obtain and keep current a D–U–N–S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: *https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm.*

4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information

1. Application Kits

Application kits/Program Instructions are available at *www.grantsolutions.gov.* Instructions for completing the application kit will be available on the site.

2. Submission Dates and Times

To receive consideration, applications must be submitted by 11:59 p.m. Eastern time on August 31, 2015, through *www.GrantSolutions.gov.*

VII. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration on Aging, Office of Healthcare Information and Counseling, Washington, DC 20201, attention: Katherine Glendening or by calling 202–357–3859, or by email *Katherine.Glendening@acl.hhs.gov.*

Dated: June 29, 2015.

Kathy Greenlee,

Administrator and Administration on Aging.

[FR Doc. 2015–16509 Filed 7–6–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2244

Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Patients With Chronic Obstructive Pulmonary Disease; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality in Patients With Chronic Obstructive Pulmonary Disease.'' This draft guidance provides a qualified context of use (COU) for plasma fibrinogen in interventional clinical trials of chronic obstructive pulmonary disease (COPD) subjects at high risk for exacerbations and/or all-cause mortality. This draft guidance also describes the experimental conditions

and constraints for which this biomarker is qualified through the Center for Drug Evaluation and Research (CDER) Biomarker Qualification Program. This biomarker can be used by drug developers for the qualified COU in submissions of investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker.

In the **Federal Register** of January 7, 2014, FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify drug development tools (DDTs) and to make new DDT qualification recommendations available on FDA's Web site. The qualification recommendations in this draft guidance were developed using the process described in that guidance.

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 September 8, 2015.

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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: Marianne Noone, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4528, Silver Spring, MD 20993–0002, 301–796–2600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Chronic Obstructive Pulmonary Disease.'' This draft guidance provides qualification recommendations for the use of plasma fibrinogen, measured at baseline, as a prognostic biomarker to enrich clinical trial populations of COPD subjects at high risk for exacerbations and/or all-cause mortality for inclusion in interventional clinical trials. This biomarker should be considered with other subject demographic and clinical characteristics, including a prior history of COPD exacerbations, as an enrichment factor in these trials.

Specifically, this draft guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. Qualification of this biomarker for this specific COU represents the conclusion that analytically valid measurements of the biomarker can be relied on to have a specific use and interpretable meaning. This biomarker can be used by drug developers for the qualified COU in submission of IND applications, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. ''Qualification'' means that the use of this biomarker in the specific COU is not limited to a single, specific drug development program. Making the qualification recommendations widely known and available for use by drug developers will contribute to drug innovation, thus supporting public health.

As stated previously, in the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a final guidance for industry entitled ''Qualification Process for Drug Development Tools'' that described the process that would be used to qualify DDTs and to make new DDT qualification recommendations available on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* The current draft guidance is an attachment to that final guidance.

CDER has initiated this formal qualification process to work with developers of these biomarker DDTs to guide them as they refine and evaluate DDTs for use in the regulatory context. Once qualified, DDTs will be publicly available for use in any drug development program for the qualified COU. As described in the January 2014 guidance, biomarker DDTs should be developed and reviewed using this process. For more information on FDA's DDTs Qualification Programs, refer to the following Web site: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm.*

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 the use of plasma fibrinogen as an enrichment biomarker in interventional clinical trials of COPD patients. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance contains an information collection that is 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 information collection has been approved under the OMB control numbers 0910–0001 and 0910–0014. The information requested in this guidance is currently submitted to FDA to support medical product effectiveness (see 21 CFR 312.30, 21 CFR 314.50(d)(5), and 21 CFR 314.126(b)(6)).

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 either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: June 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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