ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|---|
| Individuals Responding to Initial Phone Call Who Refuse to be Screened. | Screening Interview Guide | 1,250 | 1 | 1/60 |
| Individuals Responding to Initial Phone Call Responding to Screening Questions. | Screening Interview Guide | 750 | 1 | 5/60 |
| Study Participants | Baseline Interview Guide | 500 | 1 | 10/60 |
| Study Participants | MPT | 250 | 1 | 30/60 |
| Study Participants | Follow-up Interview Guide | 450 | 1 | 10/60 |

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

[FR Doc. 2016–21922 Filed 9–12–16; 8:45 am]

**BILLING CODE 4163–18–P**

## 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; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Patients With Chronic Obstructive Pulmonary Disease.'' This 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 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.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comment as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2015–D–2244 for ''Qualification for the Use of Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Patients with Chronic Obstructive Pulmonary Disease; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/*

*regulatoryinformation/dockets/default.htm.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this 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 guidance document.

**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 guidance for industry entitled ''Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Patients With Chronic Obstructive Pulmonary Disease.'' In the **Federal Register** of January 7, 2014 (79 FR 831), FDA announced the availability of a 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 at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* The qualification recommendations in the current guidance were developed using the process described in that 2014 guidance, and the current guidance is an attachment to that 2014 guidance.

Later, in the **Federal Register** of July 7, 2015 (80 FR 38694), FDA announced the availability of a draft guidance entitled ''Qualification of Biomarker—Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality for Patients With Chronic Obstructive Pulmonary Disease.'' The Agency did not receive any comments on that draft guidance during the public comment period. The current guidance finalizes that draft guidance.

This guidance provides 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 guidance provides the COU for which this biomarker is qualified through the CDER Biomarker Qualification Program. ''Biomarker qualification'' is a conclusion that within the stated COU, the biomarker can be relied upon to have a specific interpretation and application in drug development and regulatory review. 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 context in submission of INDs, NDAs, and BLAs without the relevant CDER review group reconsidering and reconfirming the suitability of the biomarker. After a biomarker is qualified for the specific COU, its qualification 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.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers, clinical outcome assessments, and animal models under the animal rule. Refer to DDTs Qualification Programs at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentTools QualificationProgram/default.htm* for additional information.

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, biomarker 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.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on 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 guidance 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. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–21964 Filed 9–12–16; 8:45 am]

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