4164-01-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in Studies Examining Exacerbations and/or All-Cause Mortality for Patients With Chronic Obstructive Pulmonary Disease; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Qualification of Biomarker--Plasma Fibrinogen in Studies Examining Exacerbations and/or All-Cause Mortality in Patients With Chronic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 This draft guidance provides a qualified context of use (COU) for plasma fibrinogen in interventional clinical trials of chronic obstructive pulmonary disease (COPD) subjects at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 This draft guidance also describes the experimental conditions and constraints for which this biomarker is qualified through the Center for Drug Evaluation and Research (CDER)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 The qualification recommendations in this draft guidance were developed using the process described in that guidance.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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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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