4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0432]

Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics; 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 guidance for industry entitled "Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics." This guidance provides recommendations to applicants on endpoints for cancer clinical trials submitted to FDA to support effectiveness claims in new drug applications, biologics license applications, or supplemental applications for the treatment of non-small cell lung cancer. This guidance focuses on endpoints specifically for lung cancer trials to support drug approval or labeling claims. This guidance should speed the development and improve the quality of protocols submitted to FDA to support anticancer effectiveness claims. This guidance finalizes the draft guidance issued on June 17, 2011.

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

ADDRESSES: 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; or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, 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.

Submit electronic comments on the 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: Rajeshwari Sridhara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3512, Silver Spring, MD 20993-0002, 301-796-1759; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics." FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee. This guidance provides background information and general principles. The endpoints discussed in this guidance are for drugs to treat patients with existing non-small cell lung cancer. This guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

This guidance finalizes the draft guidance for industry entitled "Clinical Trial Endpoints for the Approval of Non-Small Cell Lung Cancer Drugs and Biologics" issued June 17, 2011 (76 FR 35450). Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration by FDA in finalizing this guidance and some of the changes are summarized here. Sections II.A. and III. have been clarified based on the comments received and FDA's current thinking and practice regarding the magnitude of treatment effect based on progression-free survival. Appendices C and D have also been clarified based on the comments received and FDA's view on primary and sensitivity analyses of progression-free survival. The language in the guidance has been simplified to be concise.

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 clinical trial endpoints for the approval of non-small cell lung cancer drugs and biologics. 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 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 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910-0014, 0910-0001, and 0910-0338, respectively.

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/default.htm, or http://www.regulations.gov.

Dated: April 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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