Testimonies may also be submitted to this email address: *Paige.Hausburg@acf.hhs.gov.* Registration to attend the consultation can be done using this link: *http://events.constantcontact.com/register/event?llr=vt7m85dab&oeidk=a07eau2syfc09b2fe8f.*

Please register by May 18, 2015, so that OCSE can include everyone registered in the building access system to assure their entry. OCSE is located in a federal building and the security protocol requires government identification.

OCSE understands that resources are limited and travel may not be possible for some tribal leaders. In order to engage as many tribal leaders as possible, individuals who are unable to travel to Washington, DC, can connect to the meeting via a conference call. The call-in number is 1–866–642–2926, participant passcode is 1436048. The URL for the webinar is: *http://hhs.adobeconnect.com/drotribal/.* To join by phone, please register using the link above.

Dated: April 16, 2015.

Donna Bonar,

Deputy Commissioner, Office of Child Support Enforcement.

[FR Doc. 2015–09351 Filed 4–21–15; 8:45 am]

BILLING CODE 4184–41–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 This guidance finalizes the draft guidance issued on June 17, 2011.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/*

GuidanceCompliance RegulatoryInformation/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.

[FR Doc. 2015–09303 Filed 4–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–M–1452, FDA–2014–M–1596, FDA–2014–M–1597, FDA–2014–M–1599, FDA–2014–M–1735, FDA–2014–M–1736, FDA–2014–M–2042, FDA–2014–M–2246, FDA–2014–M–2248, and FDA–2014–M–2376]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2014, through December 31, 2014. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2014, THROUGH DECEMBER 31, 2014

PMA No., Docket No.	Applicant	Trade name	Approval date
P040037/S060, FDA–2014–M–1452	W.L. Gore & Associates, Inc.	GORE VIABAHN Endoprosthesis, GORE VIABAHN Endoprosthesis with Heparin.	September 19, 2014.
P070015/S122, FDA–2014–M–1596	Abbott Vascular, Inc	XIENCE V® and XIENCE nano® Everolimus Eluting Coronary Stent System.	October 3, 2014.
P110019/S066, FDA–2014–M–1596	Abbott Vascular, Inc	XIENCE PRIME® and XIENCE PRIME LL Everlimus Eluting Coronary Stent System.	October 3, 2014.
P130024, FDA–2014–M–1597	Lutonix, Inc	Lutonix 035 Drug Coated Balloon PTA Catheter.	October 9, 2014.
P110023/S007, FDA–2014–M–1599	ev3, Inc	EverFlex™ Self-Expanding Peripheral Stent System.	October 10, 2014.
P120005/S018, FDA–2014–M–1735	Dexcom, Inc	Dexcom G4™ PLATINUM Continuous Glucose Monitoring System.	October 21, 2014.
P130026, FDA–2014–M–1736	St. Jude Medical	TactiCath Quartz® Catheter and TactiSysQuartz® Equipment.	October 24, 2014.
P120011, FDA–2014–M–2042	Ideal Implant, Inc	IDEAL IMPLANT® Saline-filled Breast Implant	November 14, 2014.
P130007, FDA–2014–M–2246	Animas Corp	Animas Vibe System	November 25, 2014.
P140020, FDA–2014–M–2248	Myriad Genetic Laboratories, Inc.	BRACAnalysis CDx™	December 19, 2014.
P020012/S009, FDA–2014–M–2376	Suneva Medical, Inc	Bellafill	December 23, 2014.