Secretary, 600 Pennsylvania Avenue NW., Washington, DC 20580, 202–326–2515.

SUPPLEMENTARY INFORMATION:

Open Meeting

(1) Oral Argument In the Matter of ECM BioFilms, Inc., et al., Docket No. 9358.

Closed Meeting

(2) Executive Session to follow Oral Argument in ECM BioFilms, Inc., et al., Docket No. 9358.

Record of Commission's Vote

On April 15, 2015, Commissioners Ramirez, Brill, Ohlhausen, Wright, and McSweeny were recorded as voting in the affirmative to close Matter number (2), and to withhold from this meeting notice such information as is exempt from disclosure under 5 U.S.C. 552b(c)(10).

Commission's Explanation of Closing

The Commission has determined that Matter number (2) may be closed under 5 U.S.C. 552b(c)(10), and that the public interest does not require the matter to be open.

General Counsel Certification

The General Counsel has certified that Matter number (2) may properly be closed, citing the following relevant provision: 5 U.S.C. 552b(c)(10).

Expected Attendees

Expected to attend the closed meeting are the Commissioners themselves, an advisor to one of the Commissioners, and such other Commission staff as may be appropriate.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–09392 Filed 4–21–15; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Support Enforcement; Notice of Consultation

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of Tribal Consultation.

SUMMARY: The Department of Health and Human Services, Administration for Children and Families (ACF), Office of Child Support Enforcement (OCSE) will host a Tribal Consultation to consult on the implementation of Section 302 of Public Law 113–183, the Preventing Sex Trafficking and Strengthening Families Act of 2014 (Act).

DATES: May 20, 2015

ADDRESSES: 901 D Street SW., Room 4 E 8, the Aerospace Building, Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Paige Hausburg, Tribal Coordinator, OCSE, at (202) 401–5635, by email at *Paige.Hausburg@acf.hhs.gov,* or by mail at 370 L'Enfant Promenade SW., 4th Floor East, Washington, DC 20447.

SUPPLEMENTARY INFORMATION: On September 29, 2014, the President signed Public Law 113–183, the Preventing Sex Trafficking and Strengthening Families Act of 2014 (Act). Section 302 of the Act, which authorizes direct access to the Federal Parent Locator Service (FPLS), is below.

Section 302. Child Support Enforcement Programs for Indian Tribes

a. Tribal Access to the FPLS. The law amends section 453(c)(1) of the Act to add an agent or attorney of an ''Indian tribe or tribal organization [as defined in subsections (e) and (l) of section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b)]'' as an additional authorized person that the FPLS may provide information for the purpose of establishing parentage or establishing, setting the amount of, modifying, or enforcing child support obligations.

b. Waiver Authority for Indian Tribes or Tribal Organizations Operating Child Support Enforcement Programs. The law amends section 1115(b) of the Act to provide that an Indian tribe or tribal organization operating a IV–D program shall be considered a state for purposes of authority to conduct an experimental, pilot, or demonstration project. The Secretary may waive compliance with any requirements or regulations to the extent and for the period the Secretary finds necessary for an Indian tribe or tribal organization to carry out such project. Costs of the project that would not otherwise be included as expenditures of a program shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under a tribal plan or plans approved under such section or for the administration of such tribal plan or plans as may be appropriate. A start-up program is not eligible for this program.

On October 16, 2014, OCSE hosted a Tribal IV–D Directors call to discuss Section 302. During that call, OCSE described FPLS access to the National Directory of New Hires (NDNH), Federal Case Registry (FCR), External locates, Multistate Financial Institution Data Match (MSFIDM) and Insurance Match (IM).

On January 14, 2015, OCSE sent an email message to the Tribal IV–D Director's listserv to inform directors that OCSE was conducting an analysis of tribal access to key FPLS functions including the NDNH, FCR, External locates, Department of Defense (DOD) Entitlements, and Employer Search, using the federal Child Support portal. OCSE can provide access to these functions via the internet without tribal cases being registered on the FCR or debtors being submitted for MSFIDM and IM.

During consultation OCSE wants to discuss and gather information about the implications and responsibilities of FPLS access.

Discussion Topics

- What FPLS access means
- Requirements and design
- Discussion about the legislative requirements for fees
  - Required by statute to charge a fee for FPLS data
  - Standard fee methodology that is designed to distribute costs to all users
  - Start-up fee to cover additional administrative and development costs
  - How fees will be paid
- Security agreements
  - Security posture, security controls, and how the FPLS data is protected
  - Required physical security
  - Required security agreements
- Training for access
  - OCSE training
  - Best method/frequency for training
- Phased access of FPLS
  - Locates, FCR Query, DOD Entitlements, and Employer Search
  - Tribal cases on the FCR
  - MSFIDM and IM—to take advantage of these remedies cases must be on the debtor file
- Conversations with Tribal IV–D Directors
  - Number and Frequency of meetings
- Project Plan
  - Requirements/analysis/design by August 2015
  - Development and testing by January 2016
  - Implementation and Training January–February 2016

Testimonies should be submitted no later than May 15, 2015, to: Vicki Turetsky, Commissioner, Office of Child Support Enforcement, 370 L'Enfant Promenade SW., Washington, DC 20447.

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/*