with BP in a Consent Decree approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in the Louisiana Restoration Area are now chosen and managed by the Louisiana TIG. The Louisiana TIG is composed of the following Trustees: CPRA, LOSCO, LDEQ, LDWF, LDNR, EPA, DOI, NOAA, USDA.

Background

In the December 2017 Draft RP/EA #2, the Louisiana TIG presented to the public its plan for providing partial compensation for recreational use services lost as a result of the *Deepwater Horizon* oil spill. The public comment period for the Draft RP/EA #2 began on December 20, 2017, and closed on February 2, 2018. The Louisiana TIG hosted a public meeting on January 24, 2018, in New Orleans. The Draft RP/EA #2 proposed four restoration projects, evaluated in accordance with OPA and NEPA, including the Elmer's Island Access project. As proposed, the Elmer's Island Access project would enhance recreational opportunities within the Elmer's Island Refuge by incorporating a suite of features to improve upon existing access points, enhance the natural features of the area through reconnected hydrology, and develop a solution for improved access for recreational fishing activities targeting the eastern portion of Elmer's Island adjacent to Caminada Pass. In response to the public comments received on the Elmer's Island Access project proposed in the Draft RP/EA #2, the Louisiana TIG is proposing a modification to the original project feature. This modification would eliminate the proposed boardwalk and associated small boat launch and parking area at Elmer's Island, and provide a beach shuttle service that would allow improved public access to Caminada Pass, the most popular location for recreational fishing on Elmer's Island. The Louisiana TIG has prepared the Draft Supplemental RP/EA to inform the public about the proposed modification to the Elmer's Island Access project and to seek public comment.

Next Steps

The public is encouraged to review and comment on the Draft Supplemental RP/EA. A public meeting is scheduled to also help facilitate the public review and comment process. Comments provided on the Draft Supplemental RP/EA will be considered along with comments previously received on the Draft RP/EA #2. A summary of comments received on the Draft Supplemental RP/EA and the Draft RP/EA #2 and the Louisiana TIG's responses, where applicable, will be included in the Final Restoration Plan/Environmental Assessment #2: Provide and Enhance Recreational Opportunities (Final RP/EA #2). Public comments on the Draft Supplemental RP/EA will inform the Louisiana TIG's decision on whether to select the Elmer's Island Access project, as modified, in the Final RP/EA #2.

Administrative Record

The documents comprising the Administrative Record for the Draft Supplemental RP/EA can be viewed electronically at *http://www.doi.gov/deepwaterhorizon/administrativerecord.*

Authority

The authority for this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*), its implementing NRDA regulations found at 15 CFR part 990, and NEPA (42 U.S.C. 4321 *et seq.*).

Dated: May 3, 2018.

Benita Best-Wong,

Acting Principal Deputy Assistant Administrator, Office of Water.

[FR Doc. 2018–10112 Filed 5–18–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9039–04–OP]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7156 or *https://www2.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements
Filed 05/07/2018 Through 05/11/2018
Pursuant to 40 CFR 1506.9

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-nepa-public/action/eis/search.*

EIS No. 20180095, Final, USFWS, CA, Final Environmental Impact Statement/Environmental Impact Report for the South Sacramento Habitat Conservation Plan, Review Period Ends: 06/21/2018, Contact: Nina Bicknese 916–414–6633.

EIS No. 20180096, Final Supplement, BLM, CA, Palen Solar Project (formerly Palen Solar Power Project), Final Supplemental Environmental Impact Statement/Environmental Impact Report/Land Use Plan Amendment, Review Period Ends: 06/21/2018, Contact: Mark DeMaio 760–833–7124.

EIS No. 20180097, Final, USFS, CO, Travel Management—Rico West Dolores Roads and Trails Project, Review Period Ends: 06/21/2018, Contact: Deborah Kill 970–882–6822.

EIS No. 20180098, Final, USFS, MT, Starry Goat, Review Period Ends: 06/21/2018, Contact: Lisa Osborn 406–295–7426.

EIS No. 20180099, Draft, FAA, AZ, Tucson International Airport—Airfield Safety Enhancement Project, Comment Period Ends: 07/09/2018, Contact: David B. Kessler, AICP 310–725–3615.

EIS No. 20180100, Final, USFS, CO, P District-wide Salvage Project, Review Period Ends: 07/05/2018, Contact: Mike Tooley 719–274–6321.

EIS No. 20180101, Draft Supplement, Caltrans, CA, SR 710 North Study FRDEIR/SDEIS_05–09–18, Comment Period Ends: 07/05/2018, Contact: Jason Roach 213–897–0357.

EIS No. 20180102, Draft, NMFS, FL, Coral Habitat Areas Considered for Habitat Areas of Particular Concern Designation in the Gulf of Mexico, Comment Period Ends: 07/05/2018, Contact: Lauren Waters 727–209–5991.

EIS No. 20180103, Final, USFWS, CA, Otay River Estuary Restoration Project, South San Diego Bay Unit of the San Diego Bay National Wildlife Refuge, California, Final Environmental Impact Statement, Review Period Ends: 06/21/2018, Contact: Brian Collins 619–575–2704.

Dated: May 17, 2018.

Brittany Bolen,

Acting Assistant Administrator, Office of Policy.

[FR Doc. 2018–10937 Filed 5–18–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6759]

Establishing Effectiveness for Drugs Intended To Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders; 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 ''Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders.'' This guidance provides recommendations for establishing clinical effectiveness for drugs intended to treat male hypogonadotropic hypogonadism associated with obesity and other conditions that do not cause structural disorders of the hypothalamus or pituitary gland. This guidance incorporates advice FDA received at a December 2014 advisory committee meeting on the appropriate indicated population for testosterone therapy and a December 2016 advisory committee meeting on hypogonadotropic hypogonadism. This guidance finalizes the draft guidance of the same name issued on January 3, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 21, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–D–6759 for ''Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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: Jeannie Roule, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 5332, Silver Spring, MD 20993–0002, 301–796–3993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Establishing Effectiveness for Drugs Intended to Treat Male Hypogonadotropic Hypogonadism Attributed to Nonstructural Disorders.'' This guidance provides recommendations for establishing clinical effectiveness for drugs intended to treat male hypogonadotropic hypogonadism associated with obesity and other conditions that do not cause structural disorders of the hypothalamus or pituitary gland. This guidance incorporates advice FDA received at a December 2014 advisory committee meeting on the appropriate indicated population for testosterone therapy and a December 2016 advisory committee meeting on hypogonadotropic hypogonadism. This guidance finalizes the draft guidance of the same name issued on January 3, 2018 (83 FR 383). The guidance includes editorial changes and a new sentence clarifying that the recommendations do not apply to testosterones and testosterone esters seeking the traditional indication of replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

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 establishing effectiveness for drugs intended to treat male hypogonadotropic hypogonadism attributed to nonstructural disorders. 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: May 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10732 Filed 5–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2018–D–1711]

Cytomegalovirus in Transplantation: Developing Drugs To Treat or Prevent Disease; Draft 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 draft guidance for industry entitled ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease.'' The purpose of this guidance is to assist sponsors in all phases of development of drugs and biologics for the treatment or prevention of cytomegalovirus (CMV) disease in patients who have undergone solid organ transplantation (SOT) or hematopoietic stem cell transplantation (HSCT).

DATES: Submit either electronic or written comments on the draft guidance by July 20, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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 2018–D–1711 for ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent