

South Dakota—Best Western Ramkota Hotel and Conference Center, 2111 N. LaCrosse Street, Rapid City, SD 57701.

FOR FURTHER INFORMATION CONTACT: Robert Bialas, Regional Program Manager, Region XI, Office of Head Start, email Robert.Bialas@acf.hhs.gov or phone (202) 205-9497. Additional information and online meeting registration is available at http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) announces Office of Head Start (OHS) Tribal Consultations for leaders of Tribal Governments operating Head Start and Early Head Start programs. As much as possible, the OHS Tribal Consultations are being scheduled in conjunction with other tribal events. The Consultation in Fairbanks will be held in conjunction with the Alaska Federation of Natives Annual Convention. The Consultation in Rapid City will be held in conjunction with the National Indian Education Association's 44th Annual Convention and Trade Show. Such scheduling is an effort to minimize the burden of travel for tribal participants.

The agenda for the scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian/Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2012 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for these Consultation Sessions should contact Robert Bialas at Robert.Bialas@acf.hhs.gov. Proposals must be submitted at least 3 days in advance of each session and should include a brief description of the topic area, along with the name and contact information of the suggested presenter.

The Consultation Session will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C. 9835, 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the tribe. The letter should be submitted at least 3 days in advance of the Consultation Session to Robert Bialas via fax at 866-396-8843. Other representatives of tribal organizations and Native

nonprofit organizations are welcome to attend as observers.

A detailed report of the Consultation Session will be prepared and made available within 45 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Robert Bialas at Robert.Bialas@acf.hhs.gov either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in each report without attribution, along with topics of concern and recommendations. Hotel and logistical information for the Consultation Session has been sent to tribal leaders via email and posted on the Early Childhood Learning and Knowledge Center Web site at http://eclkc.ohs.acf.hhs.gov/hslc/eclkc_main_calendar/tc-2013.

Dated: September 16, 2013.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1039]

Draft Guidance for Industry on Endocrine Disruption Potential of Drugs: Nonclinical Evaluation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Endocrine Disruption Potential of Drugs: Nonclinical Evaluation." This draft guidance provides recommendations to sponsors on the parameters that should be routinely assessed in toxicology studies for investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) regulated by the Center for Drug Evaluation and Research to determine the potential for a drug to disrupt the endocrine system. This draft guidance also discusses factors to consider in determining the need for additional studies to characterize potential endocrine disruptor properties of a drug.

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 November 19, 2013.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993-0002, 301-796-0175.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Endocrine Disruption Potential of Drugs: Nonclinical Evaluation." Endocrine disruptors are compounds that have the potential to interfere with some aspect of the endocrine system of an organism or its progeny. Any component of the endocrine system can be a target of endocrine disruptors, although the systems most commonly affected include the sex hormones (e.g., estrogen and androgen), the hypothalamic-pituitary-adrenal axis, the thyroid hormone, and the hormones involved in the feedback regulation of those components (e.g., gonadotropin releasing hormone and corticotropin). Changes in endocrine function can result in transgenerational effects (e.g., through epigenetic mechanisms). Epigenetic modifications are heritable changes in gene function that occur in the absence of changes to the nucleotide sequence. Because such changes can be maintained and transmitted through the germ cells, these modifications can affect gene actions across generations.

This draft guidance provides recommendations to sponsors on the

parameters that should be routinely assessed in toxicology studies for INDs, NDAs, and BLAs that are designed to determine the potential for a drug to disrupt the endocrine system. This draft guidance also discusses factors that should be considered in determining the need for additional studies to characterize potential endocrine disruptor properties of a drug.

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 nonclinical evaluation of endocrine disruption potential of drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft 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 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, 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 either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft NIH Genomic Data Sharing Policy Request for Public Comments

SUMMARY: The National Institutes of Health (NIH) is seeking public comments on the draft Genomic Data Sharing (GDS) Policy that promotes sharing, for research purposes, of large-scale human and nonhuman genomic¹ data generated from NIH-supported and NIH-conducted research.

DATES: To ensure that your comments will be considered, please submit your response to this Request for Comments no later than 60 days after publication of this notice.

ADDRESSES: Submit comments by any of the following methods:

- *Online:* <http://gds.nih.gov/survey.aspx>.
- *Fax:* 301–496–9839.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions) to:* Genomic Data Sharing Policy Team, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

FOR FURTHER INFORMATION CONTACT:

Genomic Data Sharing Policy Team, Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301–496–9838, GDS@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. The draft GDS Policy supports this mission by promoting the sharing of genomic research data, which maximizes the knowledge gained. Not only does data sharing allow data generated from one research study to be used to explore a wide range of additional research questions, it also enables data from multiple projects to be combined, amplifying the scientific value of data many times. Broad research use of the data enhances public benefit by helping to speed discoveries that increase the understanding of biological processes that affect human health and the development of better ways to diagnose, treat, and prevent disease.

The NIH has promoted data sharing for many years, and in 2003, the NIH issued a general policy for sharing research data.^{2,3} In 2007, the NIH issued a more specific policy to promote

sharing of data generated through genome wide association studies (GWAS),^{4,5} which examine thousands of single nucleotide polymorphisms (SNPs) across the genome to identify genetic variants that contribute to human diseases, conditions, and traits. To facilitate the sharing of genomic and phenotypic data from GWAS, the NIH created the database of Genotypes and Phenotypes (dbGaP) with a two-tiered system for distributing the data: Open access, for data that are available to the public without restrictions, and controlled access for data that are made available only for research purposes that are consistent with the original informed consent under which the data were collected.

Not long after the GWAS policy was issued, advances in DNA sequencing and other high-throughput technologies, and a steep drop in DNA sequencing costs, enabled the NIH to fund research that generated even greater volumes of GWAS and other types of genomic data. In 2009, the NIH announced⁶ its intention to extend the GWAS Policy to encompass data from a wider range of genomic research.

The draft GDS Policy applies to research involving nonhuman genomic data as well as human data that are generated through array-based and high-throughput genomic technologies (e.g., SNP, whole-genome, transcriptomic, epigenomic, and gene expression data). (See section II of the draft Policy.) The NIH considers access to such data particularly important because of the opportunities to accelerate research through the power of combining such large and information-rich datasets. The draft GDS Policy is aligned with Administration priorities and a recent directive to agencies to increase access to digital scientific data resulting from federally funded research.⁷

Overview of the Policy

The draft GDS Policy describes the responsibilities of investigators and institutions for the submission of nonhuman and human genomic data to the NIH (section IV) and the use of controlled-access data (section V). The Policy also provides expectations regarding intellectual property (section VI).

When data sharing involves human data, the protection of research participant privacy and confidentiality is paramount, and the Policy reflects the NIH's continued commitment to responsible data stewardship, which is essential to uphold the public trust in biomedical research. The draft GDS Policy, like the GWAS Policy, includes a number of provisions to protect