Dated: May 7, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods Requests the Nomination of Reference Chemicals

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests the nomination of reference chemicals, with supporting data, to be used to validate *in vitro* metabolizing systems with the potential to interact with estrogen receptors (ERs) or androgen receptors (ARs). Specifically, a list of chemicals is needed to characterize the usefulness and limitations of *in vitro* metabolizing systems for use in conjunction with ER and AR transactivation tests.

DATES: The deadline for receipt of information is June 2, 2014.

ADDRESSES: Nominated reference chemicals and associated data should be submitted electronically in Microsoft® Excel or Word formats to *niceatm@niehs.nih.gov.* A Microsoft® Excel template for data submission is available at *http://ntp.niehs.nih.gov/go/41493.*

FOR FURTHER INFORMATION CONTACT: Dr. Warren S. Casey, Director, NICEATM; email: *warren.casey@nih.gov;* telephone: (919) 316–4729.

SUPPLEMENTARY INFORMATION:

Background

Endocrine-active substances (EAS) are chemicals that interfere with normal endocrine hormone function by mimicking, blocking, or increasing their actions, thereby possibly causing adverse health effects. United States legislation (e.g., 7 U.S.C. 136, 110 Stat 1613) requires that chemicals be tested for their ability to disrupt the hormonal systems of mammals; prospective international legislative proposals may have similar requirements. Chemicals found to test positive *in vitro* as EAS may be *in vivo* endocrine disruptors. The lack of *in vitro* tools that mimic *in vivo* metabolism is the main obstacle to implementation of *in vitro* tools for EAS toxicity testing. Improved understanding of metabolic capabilities and limitations of *in vitro* toxicity testing is critical to:

- Ensure that no potentially active metabolites are missed
- Allow better interpretation of results
- Accurately predict species-specific characteristics of absorption, metabolism, and excretion

While there is a growing body of international *in vitro* test guidelines addressing EAS mechanisms and modes of action, there are few or no standardized methods to incorporate metabolic and toxicokinetic aspects into these EAS *in vitro* tests to date. *In vitro* assays for EAS should incorporate metabolic enzyme systems to better address the relevance of EAS tests to *in vivo* adverse outcome pathways.

The Organization for Economic Co-operation and Development (OECD) Validation Management Group-Non-Animal (VMG–NA) expert working group develops internationally accepted non-animal test guidelines to support various international regulatory needs for the hazard identification of potential EAS. These test guidelines describe methods and approaches capable of identifying potential EAS without the use of animals. Consistent with its purpose of evaluating alternative methods for testing chemicals and chemical products, NICEATM participates in the VMG–NA.

Test guidelines for *in vitro* assays for ER activity have been evaluated and accepted by international regulatory authorities; test guidelines for *in vitro* AR activity assays are currently in development. However, none of these *in vitro* EAS assays account for whole animal metabolism. Further development of specific tests is needed to optimize the use of *in vitro* metabolism with EAS assays. Identification of appropriate reference chemicals to check the metabolic capacity of any proposed test method is key to continued assay development. For this purpose, the VMG–NA is developing a robust list of chemicals that, when metabolized, act as ER or AR agonist or antagonists.

Request for Information

On behalf of the VMG–NA, NICEATM requests nominations of chemicals that can be used to characterize and validate *in vitro* metabolizing systems for use in conjunction with *in vitro* tests for ER and AR transactivation. Responses are requested from all interested parties, including the research community, health professionals, educators, policy makers, industry, and the public. Considerations for selection of appropriate chemicals include the ability of a chemical to act as an ER or AR agonist or antagonist and:

- Potential for metabolism to make a chemical either more potent (bioactivation) or less potent (detoxification)
- Likelihood of metabolism occurring in relevant routes of exposure and target organs
- Likelihood of metabolism occurring over a range of doses: Information on the ratio of the half maximal effective or inhibitory concentration (EC50 or IC50, respectively) of parent to daughter metabolites will be useful and there is a particular need for information pertaining to substances where biotransformation yields a very small or very large ratio of EC50/IC50 of parent to daughter metabolites
- Stability, preferably with real-time curves and consequent exposure significance of likely metabolites
- Diversity of likely and predominant biotransformative pathways
- Diversity of chemical types, use classes, and consequent applicability domains

The reference chemicals will be used to check the metabolic capacity of the *in vitro* model, including characterization of the general metabolic capacity of the cell lines. To ensure relevant use in a regulatory context, it will be necessary, where possible, to make correlations to:

(a) Relevant *in vivo* metabolic modeling (accounting for absorption, distribution, metabolism, and excretion, etc.) of plasma/blood metabolites in vertebrate animals (e.g., rat, fish, human).

(b) Data from the uterotrophic, Hershberger, and/or other relevant assays with a demonstrated high confidence in prediction of bioactivation of estrogenic or androgenic agonist and antagonist pathways, such that the true systemic *in vivo* metabolic response is addressed as accurately as possible.

When reporting the *in vitro* dose response for potential reference chemicals, the concentrations of solvent and/or carrier proteins used in the assay buffers to solubilize the reference chemicals should be described to facilitate an understanding of potential differences among new *in vitro* assays with regard to free concentrations of parent chemical and metabolites versus nominal dosages within each testing system.

Nominated reference chemicals and associated data should be submitted electronically in Microsoft® Excel or Word formats to *niceatm@niehs.nih.gov.* Data submitted can include, but need

not be limited to, citations of reports in the published literature, data from past or ongoing validation studies, data in databases, or unpublished data. A template for data submission is available at *http://ntp.niehs.nih.gov/go/41493.*

Responses to this request are voluntary. NICEATM does not intend to publish a summary of responses received or any other information provided. No proprietary, classified, confidential, or sensitive information should be included in your response. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Those submitting information should include name, affiliation, mailing address, phone, fax, email address, and sponsoring organization (if any) with the submission. The deadline for receipt of the requested information is June 2, 2014.

Background Information on NICEATM

NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies and provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3) provides authority for ICCVAM and NICEATM to conduct activities relevant to the development of alternative test methods. Information about NICEATM and ICCVAM is found at *http://ntp.niehs.nih.gov/go/niceatm* and *http://ntp.niehs.nih.gov/go/iccvam.*

Dated: May 7, 2014.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2014–10892 Filed 5–12–14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2014–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Alabama:					
Jefferson (FEMA Docket No.: B–1403).	City of Bessemer (13–04–7454P).	The Honorable Kenneth E. Gulley, Mayor, City of Bessemer, 1800 3rd Avenue, North Bessemer, AL 35020.	City Hall, Engineering Department, 1800 3rd Avenue North, Bessemer, AL 35020.	March 13, 2014	010115
Jefferson (FEMA Docket No.: B–1403).	Unincorporated areas of Jefferson County (13–04–7454P).	The Honorable David Carrington, Chairman, Jefferson County Commission, 716 Richard Arrington, Jr., Boulevard North, Birmingham, AL 35203.	Jefferson County Land Development Department, 716 Richard Arrington, Jr., Boulevard North, Suite 260, Birmingham, AL 35203.	March 13, 2014	010217