drugshortages@fda.hhs.gov in adherence to existing recall reporting regulations (21 CFR 7.40) (OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (*see, e.g.,* § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Absenteeism guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA of Plan Activation and Deactivation	2	1	2	16	32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Absenteeism guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop Initial Plan	70	1	70	500	35,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–26527 Filed 11–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Zebrafish Embryo Chemical Screening

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests data and information on zebrafish embryo screening tests and protocol design, including pharmacokinetics measurements. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce developmental effects in offspring.

DATES: Receipt of information: Deadline is December 30, 2016.

ADDRESSES: Data and information should be submitted electronically to *niceatm@niehs.nih.gov.*

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

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, supports efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants that replace, reduce, or refine animal use. Multiple regulatory agencies require testing a substance's potential to cause developmental toxicity, which may necessitate the use of large numbers of animals.

Request for Information: NICEATM requests data and information related to chemical screening in the zebrafish embryo. Respondents should provide information on any activities relevant to the development or validation of zebrafish embryo screening assays. NICEATM is particularly interested in how the study design may influence measures of toxicity/bioactivity and the kinetics associated with chemical uptake. For comparative purposes, NICEATM also requests any available data from *in vivo* developmental studies using the same chemicals.

NICEATM specifically requests information on efforts to optimize zebrafish embryo screening tests and protocol design including comparison of (1) zebrafish strains, (2) embryos with and without an intact chorion, and (3) static and static renewal exposures. NICEATM also requests available data on chemical uptake for developing a better understanding of pharmacokinetics in the zebrafish embryo model.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is December 30, 2016. Please contact NICEATM at *niceatm@niehs.nih.gov* if you have questions or concerns about your submission. Responses to this notice will be posted at: *http://ntp.niehs.nih.gov/go/dev-nonanimal.* Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information

submitted or for its use of that information.

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. NICEATM also 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 in 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: October 27, 2016.

Linda S. Birnbaum,

Director, National Institute of Environmental, Health Sciences and National Toxicology Program.

[FR Doc. 2016–26605 Filed 11–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Availability of the Fourteenth Report on Carcinogens

SUMMARY: The Department of Health and Human Services released the 14th Report on Carcinogens (RoC) to the public on November 3, 2016. The report is available on the RoC Web site at: *http://ntp.niehs.nih.gov/go/roc* or from the Office of the RoC (see **ADDRESSES**).

DATES: The 14th RoC is available to the public on November 3, 2016.

ADDRESSES: Dr. Ruth Lunn, Director, Office of the RoC, National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, MD K2–14, Research Triangle Park, NC 27709; telephone: (919) 316–4637; FAX: (301) 480–2970; *lunn@niehs.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Questions or comments concerning the 14th RoC should be directed to Dr. Lunn (see **ADDRESSES**).

SUPPLEMENTARY INFORMATION:

Background Information on the RoC

The RoC is a congressionally mandated document that identifies and discusses agents, substances, mixtures, or exposure circumstances (collectively referred to as ''substances'') that may pose a hazard to human health because of their carcinogenicity. Substances are listed in the report as either *known* or *reasonably anticipated to be human carcinogens.* The listing of a substance in the RoC indicates a potential hazard, but does not establish the exposure conditions that pose a cancer hazard to individuals in their daily lives. For each listed substance, the RoC provides information from cancer studies that support the listing, as well as information about potential sources of exposure and current federal regulations to limit exposures. Each edition of the RoC is cumulative, that is, it lists newly reviewed substances in addition to substances listed in the previous edition. Information about the RoC is available on the RoC Web site (*http://ntp.niehs.nih.gov/go/roc*) or by contacting Dr. Lunn (see **ADDRESSES**).

NTP prepares the RoC on behalf of the Secretary of Health and Human Services. For the 14th RoC, NTP followed an established, multi-step process with multiple opportunities for public input, and used established criteria to evaluate the scientific evidence on each candidate substance under review (*http://ntp.niehs.nih.gov/go/rocprocess*).

New Listings in the 14th RoC: The 14th RoC contains 248 listings, some of which consist of a class of structurally related chemicals or agents. There are six new listings and one revised listing in this edition. The revised listing is for trichloroethylene, which was previously listed as *reasonably anticipated to be a human carcinogen* and is now listed as *known to be a human carcinogen.* Five of the new listings are in the category of *known to be a human carcinogen:* Epstein Bar virus, Kaposi sarcoma-associated herpesvirus, human T-cell lymphotropic virus type 1, human immunodeficiency virus-type 1, and Merkel cell polyomavirus. The new listing in the category of *reasonably anticipated to be a human carcinogen* is for cobalt and cobalt compounds that release cobalt ions in vivo.

Dated: October 25, 2016.

Linda S. Birnbaum,

Director, National Institute of Environmental Health Science and National Toxicology Program.

[FR Doc. 2016–26604 Filed 11–2–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. The meeting is open to the public except for parts that are closed, as indicated on the agenda. Registration is requested for both attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/165.*

DATES: *Meeting:* December 14–15, 2016, 8:30 a.m. Eastern Standard Time (EST) on both days and continues to adjournment.

Written Public Comment Submissions: Deadline is November 30, 2016.

Registration for Oral Comments: Deadline is December 7, 2016.

Registration to Attend and/or View Webcast: Deadline is December 15, 2016. Registration to view the meeting via the webcast is required.

ADDRESSES: *Meeting Location:* Rodbell Auditorium, Rall Building, National Institute of Environmental Health Sciences (NIEHS), 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at *http://ntp.niehs.nih.gov/go/165.*

Webcast: The meeting will be webcast on December 15; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for the BSC, Office of Liaison, Policy, and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 919–541–9834, Fax: 301–480–3272, Email: *whiteld@niehs.nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2124, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: Parts of the meeting are open to the public as indicated on the agenda; in-person attendance at NIEHS is limited only by the space available. Parts of the meeting