
In May 2011, the ICH Steering Committee agreed that a draft guidance entitled “Q11 Development and Manufacture of Drug Substances” should be made available for public comment. The draft guidance is the product of the Q11 Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Q11 Expert Working Group. The draft guidance describes approaches to developing process and drug substance understanding, and provides guidance on what information should be provided in sections 3.2.S.2.2 through 3.2.S.2.6 of the CTD. The draft guidance provides further clarification on the principles and concepts described in ICH guidelines “Q8 Pharmaceutical Development,” “Q9 Quality Risk Management,” and “Q10 Pharmaceutical Quality Systems” as they pertain to the development and manufacture of drug substance. The guidance is applicable to drug substances as defined in the “Scope” sections of ICH guidelines “Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances” and “Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products.” The draft guidance is intended to harmonize the scientific and technical principles relating to the description and justification of the development and manufacturing process (CTD sections 3.2.S.2.2. through 3.2.S.2.6) of drug substances (both chemical entities and biotechnological/biological entities) to enable a consistent approach for providing and evaluating this information across the three regions.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. 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. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

III. Electronic Access


Dated: June 23, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on July 27, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You”, click on “Public Meetings at the FDA White Oak Campus”. Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, e-mail: ACPS–CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On July 27, 2011, the committee will discuss current strategies for FDA’s Office of Pharmaceutical Science implementation of quality by design principles within its review offices, incorporating an update on the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Activities. The committee will also receive awareness presentations on FDA’s current partnering with the United States Pharmacopeia, principally to discuss the Monograph Modernization Program.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 20, 2011. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 11:15 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or argument they wish to present, the names and addresses of proposed participants, and an
indication of the approximate time requested to make their presentation on
or before July 13, 2011. Time allotted for
each presentation may be limited. If the
number of registrants requesting to
speak is greater than can be reasonably
accommodated during the scheduled
open public hearing session, FDA may
conduct a lottery to determine the
speakers for the scheduled open public
hearing session. The contact person will
notify interested persons regarding their
request to speak by July 14, 2011.

Persons attending FDA’s advisory
committee meetings are advised that the
Agency is not responsible for providing
access to electrical outlets.

FDA welcomes the attendance of the
core of its advisory
meetings and will make every effort to
accommodate persons with physical
disabilities or special needs. If you
require special accommodations due to
a disability, please contact Yvette
Waples at least 7 days in advance of the
meeting.

FDA is committed to the orderly
conduct of its advisory committee
meetings. Please visit our Web site at
http://www.fda.gov/
AdvisoryCommittees/
AboutAdvisoryCommittees/
ucm111462.htm for procedures on
public conduct during advisory
committee meetings.

Notice of this meeting is given under
the Federal Advisory Committee Act (5
U.S.C. app. 2).

Dated: June 23, 2011.
Jill Hartzler Warner,
Acting Associate Commissioner for Special
Medical Programs.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

New Proposed Collection; Comment
Request; Environmental Science
Formative Research Methodology
Studies for the National Children’s
Study

SUMMARY: In compliance with the
requirement of Section 3506(c)(2)(A) of
the Paperwork Reduction Act of 1995,
for opportunity for public comment on
proposed data collection projects, the
National Institute of Child Health and
Human Development (NICHD), the
National Institutes of Health (NIH) will
publish periodic summaries of proposed
projects to be submitted to the Office of
Management and Budget (OMB) for
review and approval. This proposed
information collection was previously
published in the Federal Register on
April 27, 2011, pages 23603–23605, and
allowed 60 days for public comment.
One written comment was received. The
comment questioned the cost and utility
of the study specifically and of federally
funded biomedical research in general.
The purpose of this notice is to allow an
additional 30 days for public comment.

Proposed Collection

Title: Environmental Science
Formative Research Methodology
Studies for the National Children’s
Study (NCS).

Type of Information Collection
Request: Generic Clearance.

Need and Use of Information
Collection: The Children’s Health Act of
2000 (Pub. L. 106–310) states:

(a) PURPOSE.—It is the purpose of this
section to authorize the National Institute of
Child Health and Human Development* to
conduct a national longitudinal study of
environmental influences (including
physical, chemical, biological, and
psychosocial) on children’s health and
development.
(b) IN GENERAL.—The Director of the
National Institute of Child Health and
Human Development* shall establish a
consortium of representatives from
appropriate Federal agencies (including the
Centers for Disease Control and Prevention,
the Environmental Protection Agency) to—
(1) plan, develop, and implement a
study for children’s health and development;
and
(2) investigate basic mechanisms of
developmental disorders and environmental
factors, both risk and protective, that
influence health and developmental
processes.
(c) REQUIREMENT.—The study under
subsection (b) shall—
(1) incorporate environmental
influences and outcomes on diverse
populations of children, which may include
the consideration of prenatal exposures; and
(2) gather data on environmental
influences and outcomes on diverse
populations of children, which may include
the consideration of prenatal exposures.

To fulfill the requirements of the
Children’s Health Act, the results of
formative research will be used to
maximize the efficiency (measured by
scientific robustness, participant and
infrastructure burden, and cost) of
environmental sample collection
processes and technology, storage
procedures, accompanying
questionnaires, and assays, and thereby
inform data collection methodologies
for the National Children’s Study (NCS)
Vanguard and Main Studies. With this
submission, the NCS seeks to obtain
OMB’s generic clearance to collect
environmental samples from homes and
child care settings, and conduct
accompanying short surveys related to
the physical and chemical environment.

The results from these formative
research projects will inform the
feasibility (scientific robustness,
acceptability (burden to participants
and study logistics) and cost of NCS
Vanguard and Main Study
environmental sample and information
collection in a manner that minimizes
public information collection burden
compared to burden anticipated if these
projects were incorporated directly into
either the NCS Vanguard or Main Study.

Frequency of Response: Annual As
needed on an on-going and concurrent
basis.

Affected Public: Members of the
public, researchers, practitioners, and
other health professionals.

Type of Respondents: Women of
child-bearing age, fathers, public health
and environmental science professional
organizations and practitioners, and
schools and child care organizations.
These include both persons enrolled in
the NCS Vanguard Study and their peers
who are not participating in the NCS
Vanguard Study.

Annual reporting burden: See Table 1.
The annualized cost to respondents is
estimated at: $780,000 (based on $10 per
hour). There are no Capital Costs to
report. There are no Operating or
Maintenance Costs to report.

<table>
<thead>
<tr>
<th>Data collection activity</th>
<th>Type of respondent</th>
<th>Estimated number of respondents</th>
<th>Estimated number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Estimated total annual burden hours requested</th>
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</thead>
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<tr>
<td>Home Air</td>
<td>NCS participants</td>
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<td>1</td>
<td>1</td>
<td>4,000</td>
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</tbody>
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