

Dated: November 4, 2010.

Elaine L. Baker,

Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Infectious Diseases, (BSC, OID)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 8:30 a.m.–5 p.m.,
December 6, 2010.

Place: CDC, Global Communications
Center, 1600 Clifton Road, NE., Building 19,
Auditorium B1–B2, Atlanta, Georgia 30333.

Status: Open to the public, limited only by
the space available.

Purpose: The BSC, OID, provides advice
and guidance to the Secretary, Department of
Health and Human Services; the Director,
CDC; the Director, OID; and the Directors of
the National Center for Immunization and
Respiratory Diseases, the National Center for
Emerging and Zoonotic Infectious Diseases,
and the National Center for HIV/AIDS, Viral
Hepatitis, STD, and TB Prevention, CDC, in
the following areas: strategies, goals, and
priorities for programs; research within the
national centers; and overall strategic
direction and focus of OID and the national
centers.

Matters to be Discussed: The agenda will
include OID and center updates, followed by
a focused discussion to solicit
recommendations from the board on a
strategic document designed to increase the
public health impact of CDC's infectious
disease prevention and control efforts.

Agenda items are subject to change as
priorities dictate.

Contact Person for More Information:
Robin Moseley, M.A.T., Designated Federal
Officer, OID, CDC, 1600 Clifton Road, NE.,
Mailstop D10, Atlanta, Georgia 30333,
Telephone: (404)639-4461.

The Director, Management Analysis and
Services office has been delegated the
authority to sign **Federal Register** notices
pertaining to announcements of meetings and
other committee management activities for
both CDC and the Agency for Toxic
Substances and Disease Registry.

Dated: November 4, 2010.

Elaine L. Baker,

Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities Recombinant DNA Research: Proposed Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

ACTION: Notice of consideration of
proposed actions under the *NIH
Guidelines*.

SUMMARY: A request to certify
Kluyveromyces lactis as a new host-
vector system has been submitted to the
NIH Office of Biotechnology Activities
(OBA). The data to be considered for
certifying a new host-vector system can
be found in Appendix I of the *NIH
Guidelines*. A new host-vector system
may be certified only after review by the
NIH Recombinant DNA Advisory
Committee (RAC) and specifically
approved by the NIH Director as a Major
Action.

Part of this request is to exempt from
the *NIH Guidelines* certain types of
research when performed in *K. lactis*, if
K. lactis and its affiliated plasmids meet
the requirements for certification as a
host-vector system. Research that is
exempt from the *NIH Guidelines* when
performed with other certified host-
vector systems can be found in
Appendix C of the *NIH Guidelines*.

DATES: The public is encouraged to
submit written comments on these
proposed actions. Comments may be
submitted to OBA in paper or electronic
form at the OBA mailing, fax, and e-mail
addresses shown below under the
heading **FOR FURTHER INFORMATION
CONTACT**. The NIH will consider all
comments submitted by December 1,
2010. Written comments submitted by
December 1, 2010 will be reproduced
and distributed to the RAC for
consideration at its December 7–8, 2010
meeting. In addition, an opportunity for
public comment will be provided at that
meeting. Please check the meeting
agenda for the time of this discussion
([http://oba.od.nih.gov/rdna_rac/
rac_meetings.html](http://oba.od.nih.gov/rdna_rac/rac_meetings.html)). All written
comments received in response to this
notice will be available for public
inspection at the NIH OBA office, 6705
Rockledge Drive, Suite 750, Bethesda,
MD 20892 (telephone, 301-496-9838),
weekdays between the hours of 8:30
a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT:
OBA by e-mail at oba@od.nih.gov, or
telephone at 301-496-9838, if you have
questions, or require additional

information about these proposed
actions. Comments may be submitted to
the same e-mail address or by fax at
301-496-9839 or sent by U.S. mail to
the Office of Biotechnology Activities,
National Institutes of Health, 6705
Rockledge Drive, Suite 750, MSC 7985,
Bethesda, Maryland 20892-7985. For
additional information about the RAC
meeting at which these proposed
actions will be deliberated, please visit
the NIH OBA Web site at: [http://
oba.od.nih.gov/oba/index.html](http://oba.od.nih.gov/oba/index.html).

SUPPLEMENTARY INFORMATION: OBA has
received a request from the Institutional
Biosafety Committee at New England
BioLabs to exempt from the
requirements of the *NIH Guidelines*
research with certain plasmids when
performed in *K. lactis*. In order for a
broad class of research to qualify for
exemption, it must be determined by the
NIH Director that the research does not
pose a significant risk to human health
or the environment (Section III-F-6).
One way to exempt a broad class of
research from the requirements of the
NIH Guidelines is to perform the
research in specific certified host-vector
systems (as outlined in Appendix C of
the *NIH Guidelines*). Currently research
with only three certified host-vector
systems is exempt from the *NIH
Guidelines*. These three certified
systems are based upon two bacterial
genera: *Escherichia* (*E. coli* K-12) and
Bacillus (*B. subtilis* or *B. licheniformis*)
and one lower eukaryotic genus:
Saccharomyces (*S. cerevisiae* or *S.
uvarum*). In order to certify a new host-
vector system, data as outlined in
Appendix I-II-B of the *NIH Guidelines*
must be submitted for review.
Specifically, this application will be
considered under Appendix I-II-B-1
(Host-Vector 1 Systems Other than
Escherichia coli K-12). Data to be
considered include: (i) The strain's
natural habitat and growth
requirements; its physiological
properties, particularly those related to
its reproduction, survival, and the
mechanisms by which it exchanges
genetic information; the range of
organisms with which this organism
normally exchanges genetic information
and the type of information that is
exchanged; and any relevant
information about its pathogenicity or
toxicity; (ii) a description of the history
of the particular strains and vectors to
be used, including data on any
mutations which render this organism
less able to survive or transmit genetic
information; and (iii) a general
description of the range of experiments
contemplated with emphasis on the