manufacturing of biological products other than blood and blood components. 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 requirement of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by November 13, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at http://www.fda.gov/cber/guidelines.htm.

Dated: July 6, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20158 Filed 8–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Public Health Service

The National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Center for the Evaluation of Risks to Human Reproduction (CERHR) (1) announces an upcoming evaluation of 1-bromopropane (CASRN: 106–94–5) and 2-bromopropane (CASRN: 75–26–3), (2) solicits the nomination of individuals qualified to serve on an Expert Panel, and (3) requests public input on these chemicals.

Background

The NTP and the NIEHS established the NTP CERHR (**Federal Register**, Vol. 63, No. 239, page 68782) in June 1998. The purpose of the CERHR is to provide scientifically-based, uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. A scientific expert panel reviews the scientific evidence on the chemical(s) under review, receives public comments, and then prepares a report on the chemical(s). The Expert Panel Report is made available for review and public comment on the CERHR web site (*http://cerhr.niehs.nih.gov*) and upon request from Dr. Michael Shelby, CERHR Director (see address below). Following the expert panel evaluation, the NTP staff prepares the NTP Center Report on the evaluated chemical(s). This report integrates background information on the chemical(s), findings of the expert panel, and a discussion of any pertinent studies published after the expert panel's evaluation. The NTP Center Report includes all public comments received on the Expert Panel Report. The NTP Center Report is made publicly available and is distributed to interested stakeholders and appropriate regulatory and research agencies. A summary of the complete review process was recently published in the **Federal Register** (Vol. 66, No. 136, pages 37047–37048) and can be found on the CERHR web site. A hardcopy may be requested from CERHR at the address given below.

Evaluation of 1- and 2-Bromopropane

1-Bromopropane (CASRN: 106–94–5) and 2-bromopropane (CASRN: 75–26–3) have been selected for the third CERHR expert panel evaluation. 1-Bromopropane is used as a spray adhesive; as a solvent for fats, waxes, or resins; and as an intermediate in the synthesis of other compounds. 2-Bromopropane is used in the synthesis of pharmaceuticals, dyes, and other compounds and is present as a contaminant in 1-bromopropane. Bromopropanes are being considered as replacement chemicals for hydrochlorofluorocarbons and chlorinated solvents. The scientific database on these chemicals includes studies on neurotoxicity, reproductive toxicity, and occupational exposures. 2-Bromopropane is reported to be a reproductive toxicant in humans. It is anticipated that the expert panel evaluation of 1- and 2-bromopropane will occur December 5–7, 2001, in Alexandria, VA.

An expert panel of approximately 12 scientists, selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science, will conduct these evaluations. The expert panel meeting will be open to the public with an opportunity scheduled for oral public comment.

Request for Public Input

(1) The CERHR invites input from the public on 1- and 2-bromopropane including toxicology information from completed and ongoing studies, information on planned studies, as well as current production data, human exposure information, use patterns, and environmental occurrence. Information and comments should be forwarded to Dr. Shelby at the address given below. Information and comments received by September 27, 2001 will be made available to CERHR staff and the Expert Panel and considered in the evaluation.

(2) The CERHR also invites nominations of qualified scientists to serve on the Bromopropane Expert Panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry. Criteria for listing in the CERHR Expert Registry listing include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, certification by an appropriate scientific Board or other entities, and participation in similar committee activities. Scientists on the expert panel will represent a wide range of expertise including developmental toxicology, reproductive toxicology, epidemiology, general toxicology, neurotoxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations received by September 27, 2001, publication will be considered for the Bromopropane Expert Panel and/or inclusion in the CERHR Expert Registry. Nominations should be forwarded to Dr. Shelby at the address given below.

Request for Nomination of Chemicals for Future CERHR Reviews

The CERHR welcomes the nomination of chemicals for possible future evaluation. The nominations can be made through the CERHR's web site (*http://cerhr.niehs.nih.gov*) or by contacting Dr. Shelby at the address given below.

Michael D. Shelby, Ph.D., Director, NTP Center for the Evaluation of Risks to Human Reproduction, 79 T.W.

Alexander Drive, Building. 4401, Room 102, P.O. Box 12233, EC–32, Research Triangle Park, NC 27709 Phone: (919) 541–3455, Fax: (919) 316–4511, shelby@niehs.nih.gov.

Dated: August 2, 2001.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 01–20190 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Susan S. Rucker, J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7056 ext. 245; fax: 301/402–0220; e-mail: ruckers@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Modified Leptin

YP Loh, NX Cawley (both of NICHD)
Serial No. 60/290,722 filed 14 May 2001

This invention described and claimed in this patent application provides for an improved method for producing human leptin *in vitro* or in *in vivo*. In particular, the patent application describes compositions and methods which are based on a modified form of human leptin where the regulated secretory pathway (RSP) sorting signal has been modified to provide for the constitutive secretion of leptin via the nonregulated secretory pathway (NRSP) in a mammalian cell. This invention can be applied to a non-invasive method of gene therapy to achieve sustained delivery of this therapeutic protein.

Modified Growth Hormone

YP Loh, NX Cawley (both of NICHD), BJ Baum (NIDCR), and CR Snell
Serial No. 60/290,836 filed 14 May 2001

This invention described and claimed in this patent application provides for an improved method for producing human growth hormone *in vitro* or in *in vivo*. In particular, the patent application describes compositions and methods which are based on a modified form of human growth hormone where the regulated secretory pathway (RSP) sorting signal has been modified to provide for the constitutive secretion of human growth hormone via the nonregulated secretory pathway (NRSP) in a mammalian cell. This invention can be applied to a non-invasive method of gene therapy to achieve sustained delivery of this therapeutic protein.

Dated: August 6, 2001.

Jack Spiegel,

Director, Division of Technology, Development and Transfer, Office of Technology Transfer, National Institues of Health.

[FR Doc. 01–20193 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of meetings of the National Advisory Research Resources Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Research Resources Council Executive Subcommittee.

Date: September 13, 2001.

Open: 8:00 am to 9:00 am.

Agenda: To discuss policy issues.

Place: National Center for Research Resources, National Institutes of Health, Conference Room 3B13, Building 31, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PhD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892, 301–496–6023.

Name of Committee: National Advisory Research Resources Council.

Date: September 13, 2001.

Open: 9:15 am to 3:00 pm.

Agenda: Report of Center Director and other issues.

Place: National Institutes of Health, 9000 Rockville Pike, Conference Room 10, Building 31C, Bethesda, MD 20892.

Closed: 3:00 pm to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Conference Room 10, Building 31C, Bethesda, MD 20892.

Contact Person: Louise E. Ramm, PhD, Deputy Director, National Center for Research Resources, National Institutes of Health, Building 31, Room 3B11, Bethesda, MD 20892, 301–496–6023.

Information is also available on the Institute's/Center's home page: www.ncrr.nih.gov/newspub/minutes.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: August 6, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–20207 Filed 8–10–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the