guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2737, 301–827–5848.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 24, 1998 (63 FR 39880), FDA published a notice announcing the availability of a draft guidance for industry entitled ''ANDA's: Impurities in Drug Substances.'' The draft guidance provides recommendations for including information in abbreviated new drug applications and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances. Interested persons were given until September 22, 1998, to submit written comments on the draft guidance.

On August 4, 1998, FDA received a letter from Perrigo requesting that the agency extend the comment period on the draft guidance 120 days. On August 10, 1998, FDA received a letter from the National Association of Pharmaceutical Manufacturers requesting that the agency extend the comment period on the draft guidance 60 days. On September 4, 1998, FDA received a letter from the Generic Pharmaceutical Industry Association requesting that the agency extend the comment period on the draft guidance 60 days.

This draft guidance is complex and introduces a number of new issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until November 23, 1998, to allow the public more time to review and comment on its contents.

Interested persons may, on or before November 23, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27888 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Opportunities for Cooperative Research and Development Agreements

National Cancer Institute: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the identification of analogues of wnt ligands that bind a novel soluble Frizzled-related receptor discovered at the National Cancer Institute (NCI) (the ''Technology''). Wnt proteins act as inducing agents during embryogenesis and have been implicated in the etiology of cancer. Frizzled proteins are integral membrane proteins that recently were shown to function as receptors for wnt signaling molecules. Currently, NCI has identified at least two applications for this Technology: research product and drug screening. The NCI is looking for a CRADA Collaborator with access to phage display peptide libraries for analogue screening to develop this Technology.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. § 3710; Executive Order 12591 of April 10, 1987 as amended by the National Technology Transfer and Advancement Act of 1995), the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHSS) seeks one or more CRADAs with pharmaceutical or biotechnology companies to develop this Technology.

Any CRADA for the biomedical use of this technology will be considered. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and the timely commercialization of products, diagnostics and treatments that result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or nonexclusive commercialization license to subject inventions arising under the CRADA.

ADDRESSES: Proposals and questions about these CRADA opportunities may be addressed to Vasant T. Gandhi, Technology Development and Commercialization Branch, National Cancer Institute, Executive Plaza South, Room 450, 6120 Executive Blvd., Rockville, MD 20852. Telephone: (301) 496–0477, Facsimile: (301) 402–2117. Background information, including abstracts and reprints, is available. In addition, pertinent information not yet publicly disclosed may be obtained under a confidential disclosure agreement.

EFFECTIVE DATE: In view of the high interest for developing the Technology, interested parties should notify the NCI Technology Development and Commercialization Branch in writing no later than November 18, 1998. Respondents will then be provided an additional thirty (30) days for submitting formal CRADA proposals.

SUPPLEMENTARY INFORMATION: A novel Frizzled-related soluble receptor has been expressed recombinantly and used in an ELISA format to bind protein ligand. The NCI Laboratory of Cellular and Molecular Biology (LCMB) would like to identify peptide analogs of a natural wnt ligand by using the recombinant receptor to pan phage display peptide libraries. To this end, the NCI LCMB would like to establish a CRADA with a biotechnology company possessing phage display peptide libraries and interested in participating in the screening effort. Analogs identified in this manner would be tested for agonist or antagonist activity, and might serve as prototypes of reagents capable of modulating wnt signaling associated receptor pathways.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Planning research studies and interpreting research results.

3. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Possession of a phage display peptide library.

2. Planning research studies and interpreting research results.

3. Providing support for onging CRADA-related research in the development of the particular application of the Technology.

(a) Financial support to facilitate scientific goals;

(b) Technical or financial support for further design of applications.

4. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NCI on further research and development of this Technology. This ability can be demonstrated through experience and expertise in this or related areas of Technology indicating the ability to contribute intellectually to ongoing research and development.

2. The ability to collaborate with NCI on further research and development of this Technology. This ability can be demonstrated through experience and expertise in this or related areas of Technology indicating the ability to contribute intellectually to ongoing research and development.

3. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.

4. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this Technology.

5. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of Technology.

6. The level of financial support the CRADA Collaborator will provide for CRADA-related Government activities.

7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.

8. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.

9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or nonexclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: October 8, 1998.

Kathleen Sybert,

Acting Director, Technology Development and Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 98–27963 Filed 10–16–98; 8:45 am]

BILLING CODE 4140–01–M

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 writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Agents That Bind To and Inhibit Cytochrome P450 2A6

HV Gelboin, FJ Gonzalez (NCI)
Serial No. 60/093,936 filed 23 Jul 98
Licensing Contact: Dennis Penn, 301/496–7056 ext. 211

The cytochrome P450 family of enzymes is primarily responsible for the metabolism of xenobiotics such as drugs, carcinogens and environmental chemicals, as well as several classes of endobiotics such as steroids and prostiglandins. Members of the cytochrome P450 family are present in varying levels and their expression and activities are controlled by variables such as chemical environment, sex, developmental stage, nutrition and age.

There are multiple forms of these P450 and each of the individual forms exhibit degrees of specificity towards individual chemicals of the above classes. Genetic polymorphisms of cytochrome P450 2A6 result in phenotypically distinct deficient subpopulations that differ in their ability to perform biotransformations of a particular drug and other chemical compounds.

This invention describes monoclonal antibody Mab 151–45–4, which is highly specific for human cytochrome P450 2A6 and does not cross react with 12 other human P450s. The inhibitory and immunoblotting monoclonal antibody that are described in this invention report is unique and is the only known inhibitory monoclonal antibody to human P450 2A6. Its inhibitory activity P450 2A6 is greater than 90%. This monoclonal antibody may be used as a diagnostic probe identifying the distribution of 2A6 in populations and thus identifying enzyme deficient individuals that are sensitive to 2A6 metabolized drugs. This Mab will also identify those drugs that are currently used and in the process of drug development which are substrates for 2A6. Metabolism of partner drugs by P450 2A6 may be the basis for drug-drug toxicity.

Agents That Bind To and Inhibit Human Cytochrome P450 1A2

HV Gelboin, FJ Gonzalez, TJ Yang (NCI)
Serial No. 60/093,913 filed 23 Jun 98
Licensing Contact: Dennis Penn, 301/466–7056 ext. 211

The cytochrome P450 family of enzymes is primarily responsible for the metabolism of xenobiotics such as drugs, food pyrolysate, carcinogens and environmental chemicals, as well as several classes of endobiotics such as steroids and prostaglandins. Members of the cytochrome P450 family are present in varying levels in human tissue.

There are multiple forms of these P450 and each of the individual forms exhibit metabolic activity, often overlapping, towards individual chemicals of the above classes. Genetic polymorphisms of cytochrome P450 2A6 result in phenotypically distinct subpopulations that differ in their ability to perform biotransformations of a particular drug and other chemical compounds.

This invention describes monoclonal antibodies Mab 26–7–5, Mab 951–5–1 and Mab 1812–2–4, which are highly specific for human cytochrome P450 1A2 and do not cross react with 11 other human P450s. These Mabs exhibit strong immunoblotting activity and enzyme inhibitory activity greater than 85%. The inhibitory and immunoblotting monoclonal antibody that are described in this invention report is unique and is the only known inhibitory monoclonal antibody to