DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4933]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Safety Alert/Public Health Advisory Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by April 21, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA Safety Alert/Public Health Advisory Readership Survey (OMB Control No. 0910–0341—Extension)

Section 705(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of previous alerts included spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

In the **Federal Register** of November 26, 1999 (64 FR 66479), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17[2]	157

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

[2] Due to a clerical error, the reporting burden hours for ''Hours per Response'' that appeared in the FEDERAL REGISTER of November 26, 1999 (64 FR 66480) were incorrect. Table 1 of this document contains the correct information.

Based on the history of the safety alert and the public health advisory program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: March 15, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7009 Filed 3–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Targeted Screening for Inhibitors of Human Herpesvirus 8 DNA Polymerase Activity

Opportunities for Cooperative Research and Development Agreements (CRADAs) are available for collaborations with the Screening Technologies Branch (STB), Developmental Therapeutics Program (DTP), National Cancer Institute (NCI) to discover and develop inhibitors of human herpesvirus 8 (HHV8) DNA polymerase. Collaborative projects will focus upon the inhibition of HHV8 as it relates to the disease processes of cancers which occur in patients with AIDS. This has been identified as an area of high national and international priority.

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunities for Cooperative Research and Development Agreements (CRADAs).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and 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 (DHHS) seeks one or more Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or chemical companies to discover and develop new potential antiviral (HHV8) drug leads. 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 timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA

and which are subject of the CRADA Research Plan.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820).

Scientific inquires should be submitted to Dr. Robert Shoemaker, Chief, Screening Technologies Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Bldg. 431A, P.O. Box B, Frederick MD, 21702–1201 [phone: (301)–846–5432; Fax: (301)–846–6844; e-mail shoemaker@dtpax2.ncifcrf.gov .

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential, preliminary CRADA proposals, preferably two pages or less, must be submitted to the NCI within 30 days from date of this publication. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

The Screening Technologies Branch (STB) of the Developmental Therapeutics Program is an NCI extramural research activity dedicated to the discovery of new potential lead molecules for antitumor, antiviral, or antimicrobial drug development. General background and contact information for the DTP are available on the Internet at http://www.dtp.nci.nih.gov. The STB comprises an interdisciplinary research team, and appropriate resources, expertise and experience, to carry out all essential aspects of lead-discovery, including high-throughput screening (HTS), cell-based bioassays, chemical isolation, purification and structural determinations.

STB's principal lead-discovery strategy employs high-throughput screening (HTS) to identify bioactive molecules. The sought-for bioactivity is defined by the specific type(s) of assay and/or target(s) employed in the primary screen(s) used for bioassay support of the process. In the current solicitation, CRADA partners are sought for discovery efforts targeted to the DNA polymerase and processivity factor of human herpesvirus 8. This target was cloned and characterized in the laboratory of Dr. Robert Ricciardi and is proprietary to the University of Pennsylvania. STB is implementing HTS against this target in collaboration with Dr. Ricciardi. Therefore, it is anticipated that the University of Pennsylvania will either be a third party to this CRADA collaboration or the potential CRADA collaborator would obtain rights to the target under a separate agreement with the University of Pennsylvania.

Technology Sought

STB now seeks potential collaborators with novel or distinctive pure compound collections suitable for high-throughput screening and medicinal and synthetic chemical expertise and resources for follow-up and optimization of antiviral drug leads. Primary consideration will be given to collaborators with large well-characterized chemical libraries available as individual compounds in multiwell plates. Availability of bulk compound for ''hit'' confirmation and characterization and ability to rapidly perform synthetic work to optimize lead compounds will also be major factors in consideration of potential CRADA partners.

Collaborators Sought

Accordingly, DHHS now seeks collaborative arrangements for the joint STB and collaborator discovery research and development of novel, clinically useful, antiviral (HHV8) drugs of high public health priority. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

As a minimum, the successful Collaborator should either possess broad experience in most, if not all, of the following areas; or possess highly specialized, unique expertise in one or more of the following areas, as particularly pertinent to drug lead-discovery and development: (a) creation of chemical libraries for use in high-throughput drug screening; (b) ability to carry out or direct chemical synthetic studies supporting lead-optimization, drug candidate selection and development.

NCI will provide no funding to the Collaborator in as much as financial contributions by the U.S. Government to non-Federal parties under a CRADA are not authorized under the Federal Technology Transfer Act [15 U.S.C. 3710(a)(d)(1)].

NCI and Collaborator Responsibilities

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. Providing the Collaborator with screening and test data for evaluation.
3. Planning research studies and interpreting research results.
4. Publishing research results.

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

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Providing chemical libraries for use in high-throughput screening and synthetic compounds necessary for follow-up and optimization of leads identified by screening.
3. Planning research studies and interpreting research results.
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 research and development of this technology involving lead discovery/optimization and biological evaluation. This ability can be demonstrated through experience, expertise, and the ability to contribute intellectually in this or related areas of drug discovery research and development.
2. The demonstration of adequate resources to perform the research, development and commercialization of this lead discovery/optimization and biological evaluation technology (e.g. facilities, personnel and expertise) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
3. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology as defined above.
4. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
5. 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.
6. 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 non-exclusive license to the CRADA Collaborator when the Government employee is the sole inventor.

Dated: March 7, 2000.

Kathleen Sybert,

Chief, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.

[FR Doc. 00–7050 Filed 3–21–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Steroid Derivatives with Paclitaxel-Like Activity

An opportunity is available for a Cooperative Research and Development Agreement (CRADA) for the purpose of collaborating with the Screening Technology Branch, National Cancer Institute (STB, NCI) on further research and development of U.S. government-owned technology encompassed within U.S. Provisional Patent Application Serial No. 60/161,533, entitled ''B-Homoestra-1,3,5(10)-trienes as Modulators of Tubulin Polymerization.''

AGENCY: National Cancer Institute, National Institutes of Health, PHS, DHHS.

ACTION: Notice of opportunity for cooperative research and development (CRADA).

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and 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 (DHHS) seeks a Cooperative Research and Development Agreement (CRADA) with a pharmaceutical or biotechnology company to develop new drugs and therapeutic methods based on screening pre-existing steroid libraries from the collaborator for paclitaxel-like activities and/or screening steroid derivatives from a directed synthetic effort by the collaborator to produce more active paclitaxel-like compounds. 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 timely commercialization of products or methods of treatment that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA and which are subject of the CRADA Research Plan, and can apply for background licenses to the existing patent described above, subject to any pre-existing licenses already issued for other fields of use. Dr. Mark Cushman of Purdue University is a co-inventor on the U.S. Provisional Patent Application Serial No. 60/161,533, entitled ''B-Homoestra-1,3,5(10)-trienes as Modulators of Tubulin Polymerization.'' Therefore, it is anticipated that negotiations with Purdue University regarding their interest in the original patent application would be required if the potential CRADA collaborator required exclusive rights to the technology encompassed by this patent.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Bjarne Gabrielsen, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301–846–5465, fax: 301–846–6820).

Scientific inquiries should be directed to Dr. Ernest Hamel, Senior Investigator, Screening Technology Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Bldg. 469, Rm. 237, Frederick, MD 21702–1201 [phone: (301)-846–1678; fax: (301)-846–6014]; e-mail: *hamele@dc37a.nci.nih.gov*

EFFECTIVE DATE: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential preliminary CRADA proposals, preferably two pages or less, must be submitted to the NCI on or before June 20, 2000. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists within the STB, NCI, in a collaboration with the laboratory of Dr. Mark Cushman, Purdue University, relating to steroid molecules that interact with tubulin, have discovered a subgroup of steroid derivatives that have paclitaxel-like effects on tubulin. Instead of inhibiting tubulin assembly, the new class induces formation of hyperstable microtubules and hypernucleates tubulin assembly. However, the most active molecules so far discovered are considerably less active than paclitaxel and have limited cytotoxicity. Details are in U.S. Provisional Patent Application Serial No. 60/161,533 available under an appropriate Confidential Disclosure Agreement.

Technology Sought

Accordingly, DHHS now seeks collaborative arrangements for the screening, joint elucidation, evaluation and development of novel compounds and methods to produce more active paclitaxel-like compounds. For collaboration with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

NCI and Collaborator Responsibilities

The role of the laboratory of Dr. Hamel, STB, NCI in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Undertake evaluation of compounds in their interactions with purified tubulin and examination of effects of promising compounds on cell growth and morphology. It is anticipated that such screening efforts would also reveal compounds that inhibit tubulin assembly and that have significant inhibitory effects on angiogenesis.
3. Planning research studies and interpreting research results.
4. Publishing research results.

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

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project such as lead optimization, organic synthetic efforts directed toward new analogs, derivatives.
2. Planning research studies and interpreting research results.
3. Providing technical expertise and/or financial support for CRADA-related research as outlined in the CRADA Research Plan.
4. Publishing research results.