Application no.	Drug	Applicant
ANDA 89–184	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 30 mg.	Superpharm Corp.
ANDA 89–185	Acetaminophen and Codeine Phosphate Tablets, 300 mg/ 60 mg.	Do.
ANDA 89–199	Cyproheptadine Hydrochloride Syrup, 2 mg/ 5 mL	Halsey Drug Co., Inc.
ANDA 89–362	Lidocaine Hydrochloride Injection, 20%	Abbott Laboratories.
ANDA 89–446	Chlorpropamide Tablets, 100 mg (blue)	Barr Laboratories, Inc.
ANDA 89–447	Chlorpropamide Tablets, 250 mg (blue)	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the applications listed above, and all amendments and supplements thereto, is hereby withdrawn, effective September 4, 1996.

Dated: July 9, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–19804 Filed 8–02–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute (NCI); Developmental Therapeutics Program (DTP); Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Identification, Characterization, and Development of Antibiotics From NCI's Natural Products Repository and Database of Open Compounds

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a company that can effectively pursue the preclinical identification, characterization, and development of antibiotic treatments from NCI/DTP's Natural Products Repository and Database of Open Compounds. The selected sponsor will be awarded a CRADA to establish antibiotic activity associated with such compounds.

ADDRESSES: Questions about this opportunity may be addressed to Gary Colby, or Vasiliana Moussatos, Office of Technology Development, NCI, (301) 496–0477, from whom further information may be obtained:

Address for delivery by U.S. Postal Service: Executive Plaza South, Suite 450; 6120 Executive Blvd. MSC 7182; Bethesda MD 20892–7182.

Address for delivery by messenger or overnight delivery services: 6120 Executive Blvd; Suite 450; Rockville, MD 20852.

DATES: In view of the important priority of developing new drugs for the treatment of antibiotic resistant bacteria, proposals must be received at the above address by 5:00 p.m. September 4, 1996.

TERM: The term of the CRADA will be 3 to 5 years.

SUPPLEMENTARY INFORMATION: Cooperative Research and Development Agreement or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of 1986 and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below. Under the present proposal, the Government is seeking a company which will perform the requirements set forth in the CRADA in accordance with the regulations governing the transfer of technology in which the Government has taken an active role in developing (37 CFR 404.8).

The general scope of this CRADA includes:

1. Characterizations of compounds or natural product extracts with activity against bacterial strains provided by Collaborator, including but not limited to antibiotic-resistant variants of common nosocomial infections, emerging organisms of public interest (e.g., flesh-eating bacteria), and organisms responsible for opportunistic infections (e.g., Mycobacterium spp.); (This characterization will include screening of compounds provided by NCI for this application (including previously characterized compounds in the public domain), isolation, extraction, and purification of the compound(s) present in natural product extracts, chemical characterization, and demonstration that isolation and production of the active chemical are reproducible.)

2. Using the structure(s) identified in (1), computer analyses by NCI of previously screened open NCI compounds to identify or suggest compounds that also may inhibit bacteria in (1), followed by the use of Collaborator's assays to screen and profile the NCI compounds' activity against different strains of such bacteria;

3. Modification or improvement of assays for activity against such bacterial strains in (1) based directly upon the findings in (1) and (2);

4. Addition of related bacterial strains supplied by Collaborator to this collaboration based upon this experience;

5. Synthesis of analogues of the lead structures based directly upon information gained in this collaboration; and

6. Where appropriate and under a mutually agreeable amendment, preclinical development of compounds to support clinical trials using agents for which the compelling rationale for development was identified in this collaboration.

The principal goal of the CRADA in the first year is to generate sufficient data to prove the concept that compounds exist in the NCI Natural Products Repository of crude extracts and purified chemicals which may possess activity against such bacteria listed above in (1) as provided by the Collaborator. The Collaborator will test a variety of extracts, e.g., fungal, higher plant, marine organisms, etc. selected for this purpose and provided by NCI, against said bacteria utilizing a screening and testing program which may or may not be proprietary to Collaborator such as a standard plate assay of bacterial growth or an enzyme-based screening system capable of high throughput and automation. It is further hoped that long-term results may also lead to new and novel molecular structures.

In view of the intellectual contributions of NCI, such as the creation of the ranked lists of compounds with potential to interact with such bacterial strains of interest as provided by the Collaborator, the results of this collaboration, in the form of agents with clinical potential or tools for

further scientific research, will be considered to be the results of a collaborative effort on the part of NCI and the collaborator. Inventorship and ownership of any intellectual property arising from this collaboration will be determined according to U.S. and international Patent Law with reference to the terms of the negotiated CRADA.

The role of the NCI will include *inter alia* providing nonexclusive access (unless otherwise noted) to research materials, methodology and data:

- Access to extracts (fungal, plant, marine, etc.) and other tests chemicals in the NCI Natural Products Repository and Database of Open Compounds;
- Project guidance and oversight;
- Nonexclusive access to NCI's *in vitro* cell line screening data for open samples of pure compounds or for identified Natural Product extracts found to be active in the expanded microbial screen so antibacterial activity, cell line cytotoxicity, and growth inhibition can be compared.
- Analyses of cytotoxicity/growth inhibition profiles in the NCI Tumor Cell Line Panel to identify open compounds in the NCI database possessing similar profiles as compounds established by the Collaborator as having antibiotic activity;
- Cell lines from the NCI Tumor Cell Line Panel, as well as guidance in their choice;
- Upon verification that similar cytotoxicity/growth inhibition profiles exist between compounds with antibiotic activity and open compounds in the NCI database, provision of lists, rankings and correlates of available compounds to Collaborator for verification testing. The NCI may include in these lists other compound for which there are indications of development potential against (or as markers for) such bacteria listed in (1); and
- As appropriate, performance with the collaborator of additional preclinical studies (such as tests of in vivo efficacy) if compounds meet criteria required for use of these resources.

The role of the successful company under a CRADA will include the following:

- Perform screening operations necessary to identify compounds or extracts with desired anti-bacterial properties;
- Purify and identify active molecules from active natural product extracts;
- Identify, procure and provide to NCI, cultures of such bacteria listed in (1);
- Provide expert advice and support related to safe management of such bacteria listed in (1);
- Perform verification testing of the natural products, open listed correlates and compounds of interest suggested by the NCI, using proprietary or nonproprietary assay systems developed and/or implemented by Collaborator for activity against such bacteria in (1) as well as perform potentially necessary cytotoxic and growth inhibition assays of cell lines in the NCI Tumor Cell Line Panel; and
- Provide written progress reports incorporating results to the NCI on a quarterly basis. (The NCI will alert the Collaborator to any substantive changes to the lists, ranks, or correlates as such information becomes available.)

Criteria for choosing the company include:

- Ability to provide technical screening expertise, ability to supply bacterial cultures, ability to purify active compounds from natural product mixtures;
- Ability to provide sufficient internal staffing necessary to pursue aggressively its efforts associated with the CRADA including scientific, management and administrative support;
- Demonstrated ability to develop and commercialize pharmaceutical agents or products;
- Ability to provide sufficient internal funding necessary to aggressively pursue its efforts associated with the CRADA;
- Ability to provide sufficient internal funding for materials and supplies, training and travel as required by NCI in support of its efforts under the CRADA;
- Willingness to abide by NCI policy required for the transfer of natural products from the NCI Natural Products Repository; and
- Willingness to abide substantially by the terms of the Model NIH CRADA.

The collaborator must agree to abide by the following NCI guidelines for access to natural products from the NCI Natural Products Repository.

(A) Should an agent eventually be licensed to the Collaborator or licensed or sublicensed to a pharmaceutical company for production and marketing, NCI will require the collaborator or successful licensee to negotiate and enter into agreement(s) with the Source Country Government (''SCG'') agency(ies) or Source Country Organization(s) as appropriate. This agreement(s) will address the concern on the part of the Source Country Government (''SCG'') or Source Country Organization(s) (''SCO''), that pertinent agencies, institutions, and/or persons receive royalties and other forms of compensation, as appropriate.

(B) Such terms shall apply equally to instances where the invention is the actual isolated natural product, or where the invention is a product structurally based on the isolated natural product (i.e., where the natural product provides the lead for the development of invention), though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that he eventual development of a drug to the stage of marketing is a long term process which may require 10–15 years.

(C) In obtaining additional sources of active material product extract by CRADA collaborator or licensees, the NCI will require the collaborator or applicant for license to seek as its first source of supply the natural products from Source Country. If no appropriate licensee is found who will use natural products available from Source Country, or if the Source Country Government (''SCG'') or Source Country Organization(s) (''SCO'') as appropriate, or its suppliers cannot provide adequate amounts of raw materials at a mutually agreeable fair price, the licensee will be required to pay the Source Country Government (''SCG'') or Source Country Organization(s) as appropriate, an amount of money (to be negotiated) to be used for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures. Such terms will also apply to instances where the active agent is prepared by total synthesis.

(D) Section C shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided by local residents to guided the collection of such an organism from Source Country, or unless other justification acceptable to both the Source Country Government (''SCG'') and Source Country Organization(s) (''SCO'') and the NCI is provided. In the case where an organism is freely available from different countries, but a genotype producing an active agent is found only in the Source Country, Section C shall apply.

Dated: July 26, 1996.

Thomas D. Mays,

Director, Office of Technology Development, National Cancer Institute, National Institutes of Health.

[FR Doc. 96–19847 Filed 8–2–96; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–066–06–1610–00]

Proposed California Desert Conservation Area Plan Amendment, Palm Springs-South Coast Resource Area, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: On March 15, 1996, notice was published in the Federal Register announcing availability of the Proposed California Desert Conservation Area Plan Amendment and Environmental Assessment for a 60-day public review period. In this document, two plan amendments were proposed. Amendment One proposes to expand the Big Morongo Canyon Area of Critical Environmental Concern (ACEC) from 3,075 to 29,000 acres to provide more effective management of bighorn sheep habitat, wetlands, riparian areas, wildlife corridors and other sensitive resources. The Big Morongo Canyon ACEC is located six miles north of Interstate 10, just east of Highway 62, straddling the San Bernardino-Riverside County line. Amendment Two proposes to expand the Salt Creek Desert Pupfish/Rail Habitat ACEC from 4,288 to 14,880 acres to protect palm oases, cultural resources, wildlife corridors, wetlands, endangered species habitat and other sensitive resources. The Salt Creek ACEC would also be renamed the Dos Palmas ACEC. The Salt Creek ACEC is located three miles northwest of the Salton Sea, Riverside County, California.

BLM received 12 public comment letters. BLM has reviewed these letters and has incorporated the comments into the proposed plan. BLM is prepared to proceed with the proposed Dos Palmas ACEC expansion (Amendment Two) and Big Morongo Canyon ACEC expansion (Amendment One). In accordance with title 43 of the Code of Federal Regulations part 1610.5–2, citizens with standing may protest the proposed decisions.

DATES: Protests must be submitted in writing no later than 30-days from the date of this notice to the following address: Area Manager, Bureau of Land Management, Palm Springs-South Coast Resource Area, 690 Garnet Avenue, North Palm Springs, CA 92258–2000.

FOR ADDITIONAL INFORMATION CONTACT: Elena Misquez, Bureau of Land Management, Palm Springs-South Coast Resource Area, 690 Garnet Avenue, North Palm Springs, CA 92258–2000; telephone (619) 251–4826.

SUPPLEMENTARY INFORMATION: Nothing in this Proposed Plan shall have the effect of terminating any validly issued rights-of-way or customary operation, maintenance, repair, and replacement activities in such rights-of-ways within the ACEC boundaries in accordance with Sections 509(a) and 701(a) of the Federal Land Policy Management Act of 1976.

Dated: July 26, 1996.

Julia Dougan,

Area Manager.

[FR Doc. 96–19737 Filed 8–2–96; 8:45 am]

BILLING CODE 4310–40–P

[CA–930–06–1020–00, 4000/1790]

Reopening of Scoping Period for an Environmental Impact Statement and Land Use Plan Amendment Involving the Development of Standards for Rangeland Health and Guidelines for Grazing Management on Public Lands in California and Northwestern Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: The Bureau of Land Management (BLM) in California is reopening the scoping period for a statewide Environmental Impact Statement (EIS) and land use plan amendment involving the development of Standards for Rangeland Health and Guidelines for Grazing Management as provided in the BLM's new grazing regulations (43 CFR Part 4100). The EIS is being prepared in compliance with section 102(2)(C) of the National Environmental Policy Act (NEPA). This notice invites public input on the development of the Standards and Guidelines, issues to be addressed, planning criteria, and the alternatives to be considered in the EIS.

DATES: Comments concerning the scope of the EIS and Plan Amendment must be received by September 4, 1996.

ADDRESSES: Any scoping comments or requests to be placed on the mailing list should be sent to Rangeland Health Coordinator, Bureau of Land Management, 2135 Butano Drive, Sacramento, CA 95825–0451.

FOR FURTHER INFORMATION CONTACT: Jim Morrison at (916) 979–2830.

SUPPLEMENTARY INFORMATION: The initial scoping period closed April 24, 1996. BLM is reopening the scoping period to provide the public an opportunity to focus on the efforts of the Resource Advisory Councils (RACs) or to submit additional comments on the scope of the EIS.

As indicated in the March 25, 1996 Notice of Intent, BLM's new grazing administration regulations (43 CFR Part 4100), which became effective August 21, 1995, provide for the development of state Standards for Rangeland Health and Guidelines for Grazing Management. A national programmatic EIS was completed by BLM in 1993 in support of the new regulations. This EIS for California and northwestern Nevada will be tiered to the national EIS, and will incorporate applicable information from previously prepared BLM grazing EISs.

The four RACs in California have been working with BLM in developing proposed S&Gs and alternatives. The proposed S&Gs and alternatives must address the following elements: (1) Watershed function; (2) nutrient cycling and energy flow; (3) water quality; (4) habitat for threatened and endangered species and proposed Candidate 1 or 2, or special status species; and (5) habitat quality for native plant and animal populations and communities.

BLM has preliminarily identified, with RACs involvement, three alternatives for analysis in the EIS: (1) RAC S&G Proposals: This alternative would include the recommended S&Gs of each RAC for their respective area in Bakersfield district and northern California. The California Desert District will operate under existing land use plan direction or the fall-back S&Gs, whichever is the more restrictive, until S&Gs can be developed in conjunction with bioregional plans for the West Mojave, Northern and Eastern Colorado, and Northern and Eastern Mojave Deserts, or other specific plan amendments. (2) No Action: This alternative would incorporate the fall-back S&Gs directly from the regulations; (3) Consistency: This alternative would draw from the individual RAC recommended S&Gs to formulate a consolidated set of S&Gs. It may alter some RAC recommendations or add additional S&Gs to improve consistency among the individual RACs and neighboring states of Arizona, Nevada, and Oregon. In addition to analyzing the three alternative described above, the EIS will describe existing land use plan direction.