DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Ethical Issues Associated With Nurse Practitioner and Physician Assistant Practice: A Comparative Analysis

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Department of Clinical Bioethics, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collected listed below. This proposed information collection was previously published in the **Federal Register** on January 22, 2002, page 2892 and allowed 60 days for public comment. Public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Ethical Issues Associated with Nurse Practitioner and Physician Assistant Practice: A Comparative Analysis. Type of Information Collection Request: New. Need and Use of Information Collected: The purposes of the study are (1) to examine whether the current practice environment has created ethical concerns/conflict for Nurse Practitioners and Physician Assistants in the provision of patient care; (2) to explore relationships between selected individual, organizational, and state regulatory factors and ethical conflict in practice and the perceived delivery of quality care; and (3) to examine the perceived level of ethics preparedness and confidence in ethics decision-making. The findings will provide valuable information concerning: (1) The importance of ethics and ethical factors from the perspective of different professional groups, and (2) ethics educational needs of Nurse Practitioners and Physician Assistants. Frequency of Response: Once. Affected Public: Individuals; Academic Institutions, Business or for-profit; Not-for-profit organizations. Type of Respondents: Nurse Practitioners and Physician Assistants. The annual reporting burden follows in the table below. The annualized cost to respondents is estimated at: $97,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Respondent and Burden Estimate Information

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Nurse Practitioners	1950	1	.33	643.5
Physician Assistants	1950	1	.33	643.5
Total	.....	.....	.....	1287

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Connie Ulrich, RN, PhD., Principal Investigator, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, Building 10, Room 1C118, Bethesda, MD 20892, or call non-toll-free number (301) 451–8338 or E-mail your request, including your address to *culrich@cc.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: June 3, 2002.

David K. Henderson,

Deputy Director, Warren G. Magnuson Clinical Center, National Institutes of Health.

Ezekiel J. Emanuel,

Director, Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, National Institutes of Health.

[FR Doc. 02–14438 Filed 6–7–02; 8:45 am]

BILLING CODE 4141–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''High Throughput Infrared Spectroscopy''

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

ACTION: Notice.

SUMMARY: This is a public notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license worldwide to practice the

inventions embodied in: U.S. Patent Application Nos. 60/092,769 filed July 14, 1998; 60/095,800 filed August 7, 1998; 09/353,325 filed July 14, 1999 and PCT Application No. PCT/US99/15900 filed July 14, 1999 (''High Throughput Infrared Spectroscopy'' by Neil Lewis); U.S. Patent Application Nos. 60/120,859 filed February 19, 1999; 60/143,801 filed July 14, 1999; 09/507,293 filed February 18, 2000 and PCT Application No. PCT/US00/19271 filed July 14, 2000 (''High Volume On Line Spectroscopic Composition Testing of Manufactured Pharmaceutical Dosage Units'' by Neil Lewis, David Strachan and Linda Kidder), to Spectral Dimensions, Inc., having a place of business in Olney, Maryland.

The United States of America is an assignee to the patent rights of these inventions. The field of use for the contemplated exclusive license may be limited to instrumentation for inspection of finished pharmaceuticals and drug candidate screening.

DATES: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before September 9, 2002, will be considered.

ADDRESSESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Dale D. Berkley, Ph.D., J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 496–7735, ext. 223; Facsimile: (301) 402–0220; e-mail: *berkleyd@od.nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

SUPPLEMENTARY INFORMATION: The invention is an infrared spectrometer having an array of cells with a number of cavities. A number of the cells typically contain a different reference material, and a plurality of cells are reserved to hold various samples. The cells have covers and can be individually purged before a measurement is made. Because reference and unknown samples can be processed at the same time, variation between measurements can be minimized. Using two connected cells, an instrument can monitor a reaction in real time, continuously determining relative concentrations of reagents, products and intermediates. The cells may form parts of process feed lines, such that multiple processes can be monitored in real time. The invention further comprises a pharmaceutical dosage unit manufacturing process control system that uses continuous spectral imaging to test the actual composition of pharmaceutical dosages even in packaged drugs. The system can screen for errors in coloring of ingredients, for contamination or breakdown that occurs independent of coloring and for other types of errors that might not otherwise be detected. The system can perform composition measurements through the end-user package walls to detect contamination or damage that occurs during packaging. The invention performs composition analysis by comparing spectral information with libraries of known spectral signatures, allowing small concentrations of potentially dangerous contaminants to be detected. Relative quantities of ingredients can be directly measured, such that a change in the ratio of these ingredients can be detected.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 90 days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 29, 2002.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 02–14440 Filed 6–7–02; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: ''Compound, Composition and Method For Treating Cancer'', U.S. Patent 6,235,761

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

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. § 209(c)(1) and 37 CFR part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in United States Patent number 6,235,761, entitled, ''Compound, composition and method for treating cancer,'' which was issued on May 22, 2001 and claims priority to U.S. Patent Application S/N 60/019,086, entitled, ''Compound, composition and method for treating cancer,'' which was filed on May 30, 1996, to Xanthus Life Sciences which is located in Cambridge, Massachusetts. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory will be worldwide and the field of use may be limited to human therapeutics for the treatment of cancer.

DATES: Only written comments and/or license applications that are received by the National Institutes of Health on or before August 9, 2002 will be considered.

ADDRESSES: Requests for copies of the patent, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Richard U. Rodriguez, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852–3804. Telephone: (301) 496–7056, X287; Facsimile: (301) 402–0220; and E-mail: *rodrigur@od.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology claimed in the issued patent relates to the 4-demethyl penclomedine molecule and all salts, both alone and in combination. The patent also claims use of the drug in treating cancer, especially solid tumors.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.