(minocycline hydrochloride) Capsules EQ 75 mg base (NDA 050–649), manufactured by Triax Pharmaceuticals, Ltd. (Triax), was withdrawn from sale for reasons of safety or effectiveness. MINOCIN is a tetracycline-class antibiotic medicine used to treat certain infections caused by bacteria. MINOCIN Capsules EQ 75 mg base was approved on February 12, 2001. Our records show that the 75 mg strength of this product was marketed for a short period of time in 2001. MINOCIN Capsules EQ 75 mg base were discontinued in September 2001 and the drug product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that MINOCIN Capsules EQ 75 mg base was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that MINOCIN Capsules EQ 75 mg base was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list MINOCIN (minocycline hydrochloride) Capsules EQ 75 mg base in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to minocycline hydrochloride capsules EQ 75 mg base may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: February 21, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–3879 Filed 2–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Cancer Care for Uninsured Individuals: A Feasibility Study (NCI)

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on December 21, 2007 (Vol. 72, No. 245, p. 72741 and allowed 60-days for public comment. One public comment was received that questioned why the study was not funded by University of Alabama (UAB) funds. A response was made on February 8, 2008, that indicated that UAB was funding this study. 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: Cancer Care For Uninsured Individuals: A Feasibility Study. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this information collection is to assess the feasibility of obtaining health insurance information for participants of the Prostate, Lung, Colon and Ovarian (PLCO) Cancer Screening Trial participants from health care providers and self reports. The ultimate objective is to compare the health care utilization of insured and uninsured PLCO participants. The PLCO data provides a unique opportunity to study health care seeking behavior after an abnormal cancer screening test and the effect of lack of health insurance. Participants who had positive cancer screening tests were referred to their doctors for follow-up care. No additional care was provided by the trial. The study collected detailed information on tests received for diagnosis, clinical presentation of disease, and cancer treatment. Since the PLCO original data collection had not recorded the health insurance of participants at the time of their screening, it is necessary to collect it retrospectively. This feasibility study will request information from 50 physicians and 150 participants. The aims are to determine the:

(1) Total number of physicians to be contacted to obtain insurance information on all PLCO participants who had a positive cancer screening test;

(2) Percentage of physicians willing and able to provide insurance information;

(3) Percentage of participants with and without insurance;

(4) Number of participants for whom insurance status can be only determined by self report;

(5) Percentage of PLCO participants who accept to respond to the survey;

(6) Percentage of individuals who are willing to provide information on insurance status; and,

(7) Potential proportion of PLCO participants without health insurance.

These results will be used to design a study to examine the health care behavior of insured and uninsured PLCO participants. This is relevant to understand the results of the PLCO Cancer Screening Trial and other screening trials currently being conducted in the U.S. The success of these trials is conditional on participants' access to care following a recommendation for follow-up. Uninsured individuals may be more likely to join these trials than insured ones in order to get free preventive care. They may also be more likely to not seek, or delay seeking, care after an abnormal screening test even though they are encouraged to get care and they may be highly motivated to receive the best care possible. It is relevant for other decision makers to understand whether uninsured persons are receiving appropriate care after abnormal screening results. The efforts to control cancer disease and the loss of life associated with it are concentrated on population wide screening. These endeavors may be compromised if a significant proportion of the population does not get appropriate follow-up after screening or does not get the care known to be effective for their disease. *Frequency of Response:* One time. *Affected Public:* Individuals and households; businesses or other for-profit. *Type of Respondents:* Individuals older than 55 who participated in the PLCO Screening trial and physicians who provided care for them. The annual reporting burden is shown in the following table.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Annual hour burden
PLCO participants	150	1	5 minutes (0.083)	12.5
Physicians office staff	50	1	20 minutes (0.333)	16.7
Totals	200			29.2

The annualized cost to respondents is estimated at: $487.50. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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 Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Maria Pisu, Division of Preventive Medicine, University of Alabama at Birmingham, MT 628, 1530 3rd Avenue South, Birmingham, AL 35294–4410, or call non-toll-free number (205) 975–7366 or e-mail your request, including your address to: *mpisu@uab.edu*

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: February 20, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–3836 Filed 2–28–08; 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, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

A Pharmacophore for Isatin-β-Thiosemicarbazone Compounds With MDR1-Inverse Activity

Description of Technology: One of the major hindrances to successful cancer chemotherapy is multi-drug resistance (MDR), which is frequently caused by the increased expression or activity of ABC transporter proteins. Research has generally been directed to overcoming MDR during cancer therapy by inhibiting the activity of ABC transporters. However, compounds that inhibit ABC transporter activity often elicit strong and undesirable side-effects, restricting their usefulness in therapy.

In an alternative approach to reducing the debilitating effects of MDR in cancer therapy, scientists at the National Cancer Institute identified a family of compounds whose antiproliferative effects were actually enhanced in cells with MDR. These compounds included NSC 73306, a specific compound that increased the chemosensitivity of cells that overexpress ABC transporters without inhibiting ABC transporter activity. This invention concerns new analogs of NSC 73306 with improved selectivity and solubility, and the use of the analogs as therapeutics.

Applications:

Treatment of cancers associated with multi-drug resistance, either alone or in combination with other therapeutics.

Development of a pharmacophore for improved effectiveness in treating cancers associated with multi-drug resistance.

Advantages:

The agents capitalize on one of the most common drawbacks to cancer therapies (MDR) by using it as an advantage to treating cancer.

Increased specificity allows these analogs to be tailored to treating cancers associated with the overexpression and hyperactivity of particular ABC transporters.

Increased solubility allows greater access of the agent to tumor cells, increasing therapeutic effectiveness of the agents.

Benefits: Cancer is the second leading cause of death in United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2007. Improving the quality of life and duration of life of cancer patients will depend on chemotherapies with increased effectiveness and reduced toxicity, thus this technology can contribute significantly to a social cause. Furthermore, small molecule cancer therapy technologies have a potential market of more than $2 billion.

Inventors: Matthew D. Hall et al. (NCI).