FOR FURTHER INFORMATION CONTACT:
Regarding the administrative and financial management aspects of this notice: Michelle N. Caraffa (see **ADDRESSES**).
Regarding the programmatic aspects of this notice: Stephen Toigo, Division of Federal-State Relations (DFSR), Office of Regulatory Affairs, Food and Drug Administration (HFC–150), 5600 Fishers Lane, rm. 12–07, Rockville, MD 20857, 301–827–6906, or access the Internet at: *http://www.fda.gov/ora/fed_state/default.htm*. For general ORA program information contact your Regional Food Specialists at *http://www.fda.gov/ora/fed_state/DFSR_Activities/food_specialists.htm*

On page 35653 in the first column, under section V.A, a sentence is added at the end of the paragraph that reads: ''A Current Listing of SPOCs can be found at *http://www.whitehouse.gov/omb/grants/spoc.html*.''

On page 35653 in the third column, under section VII, the paragraph is revised to read: ''Applicants are encouraged to apply electronically (see **ADDRESSES**). If not, the original and two copies of the completed grant application Form PHS–5161–1 (Revised 7/00) for State and local governments should be delivered to the Grants Management Office. The receipt date is March 15, 2005. No supplemental material or addenda will be accepted after the receipt date.''

On page 35653 in the third column, under section VIII.A in the second paragraph, the last sentence should read: ''FDA is now accepting applications via the Internet.''

Dated: January 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2209 Filed 2–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 3, 2005, from 8 a.m. to 5 p.m. and March 4, 2005, from 8 a.m. to 1 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 3, 2005, the committee will do the following: (1) Discuss new drug application (NDA) 21–115, COMBIDEX (ferumoxtran–10), Advanced Magnetics, Inc., proposed indication for intravenous administration as a magnetic resonance imaging contrast agent to assist in the differentiation of metastatic and nonmetastatic lymph nodes in patients with confirmed primary cancer who are at risk for lymph node metastases, and (2) discuss prostate cancer endpoints as a followup to the June 2004 FDA workshop. On March 4, 2005, the committee will do the following: (1) Discuss the results of a confirmatory trial for NDA 21–399, IRESSA (gefitinib) AstraZeneca Pharmaceticals LP, for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer after failure of both platinum-based and docetaxel chemotherapies, and (2) discuss safety concerns, specifically osteonecrosis of the jaw (ONJ), associated with two bisphosphonates, NDA 21–223, ZOMETA (zoledronic acid) Injection and AREDIA (pamidronate disodium for injection), both from Novartis Pharmaceuticals Corp. ZOMETA is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy. It is also approved for hypercalcemia of malignancy. AREDIA is indicated, in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. It is also indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, and treatment of patients with moderate to severe Paget's disease of bone.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 28, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on March 3, 2005, and between approximately 10:30 a.m. to 11 a.m. on March 4, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Trevelin Prysock at 301–827–7001, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 27, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–2208 Filed 2–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Development of Revised Need for Assistance Criteria for Assessing Community Need for Comprehensive Primary and Preventive Health Care Services Under the President's Health Centers Initiative

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Solicitation of comments.

SUMMARY: Currently, application scores for New Access Point (NAP) applications under the President's Health Centers Initiative (Program) cluster at the high end of the scoring range, providing little distinction among applicants. Since the intent of the Program is to provide grants to the neediest communities, HRSA is considering placing more emphasis on assessing the need for comprehensive primary and preventive health care services in the service area or for the population for which the applicant is seeking support, by revising the Need for Assistance Criteria and changing the relative weights of the review criteria used in evaluating such applications. This notice offers public and private nonprofit entities an opportunity to comment on the proposed changes in the Need for Assistance Criteria (NFA), and on the degree to which need should be weighted relative to other criteria used in evaluating future applications. In order to solicit comments from the public on these proposed changes, HRSA is delaying the due date (May 23, 2005) for the second round of fiscal year (FY) 2005 New Access Point applications.

Authorizing Legislation: Section 330(e)(1)(A) of the Public Health Service Act, as amended, authorizes support for the operation of public and nonprofit private health centers that provide health services to medically underserved populations.

Reference: For the current Need for Assistance (NFA) criteria and other application review criteria, including weights used most recently, see Program Information Notice (PIN) 2005–01, titled ARequirements of Fiscal Year 2005 Funding Opportunity for Health Center New Access Point Grant Applications,'' are available on HRSA's Bureau of Primary Health Care (BPHC) Web site at *http://bphc.hrsa.gov/pinspals/pins.htm.* That PIN detailed the eligibility requirements, review criteria, and awarding factors for applicants seeking support for the operation of New Access Points in FY 2005.

Background: The goal of the President's Health Centers Initiative, which began in FY 2002, is to increase access to comprehensive primary and preventive health care services to 1,200 of the Nation's neediest communities through new and/or significantly expanded health center access points over five years. These health center access points are to provide comprehensive primary and preventive health care services in areas of high need that will improve the health status of the medically underserved populations to be served and decrease health disparities. Services at these new access points may be targeted toward an entire community or service area or toward a specific population group in the service area that has been identified as having unique and significant barriers to affordable and accessible health care services.

While it is extremely important that NAP grant awards be made to entities that will successfully implement a viable and compliant program for the delivery of comprehensive primary health services to the populations or communities they propose to serve, HRSA also needs to assure that all applicants seeking support for a NAP applicant can demonstrate the need for such services in the community (area or population group) to be served and be evaluated on that need. Under the current guidance, NFA criteria are used to quantify barriers to access and identify health disparities. The NFA process also establishes a threshold which applicants must meet in order for their applications to be reviewed by the Objective Review Committee (ORC).

Description of Current NFA process. The current NFA process (as described in Form 9-Part A of PIN 2005–01) involves two major groups of indicators. First, from eight (8) ''Barriers and Access to Care'' measures, the applicant must select five (5). These measures are: Shortage of primary care physicians, as measured by whether the target service area has been designated as a geographic or population group Health Professions Shortage Area (HPSA); Percent of the population with incomes below 200% of the Federal poverty level; Life expectancy of target population (in years); percentage of target population uninsured; unemployment rate of target population; average travel time or distance to nearest source of primary care for target population; percentage of target population age 5 or older who speak a language other than English at home; and length of waiting time for public housing and Section 8 certificates for target population. For the first of these measures, the applicant receives 14 points if HPSA-designated and zero otherwise; for each of the other measures, the NFA criteria define a 6-level scale from 0 to 14 points. The applicant provides data for its service area or target population for each of the 5 measures selected, and identifies the source of data used. Given 5 indicators and a maximum of 14 points for each, there are a possible 70 points for the ''Barriers and Access to Care'' indicators.

Second, from 28 ''Health Disparity Factors'', the applicant selects 10 and provides data on each for its service areas or target populations. For each factor selected, the applicant can receive 3 points if the value for the target population exceeds the benchmark used. The applicant defines the benchmark, and gives a source for that benchmark as well as a source for the target population data provided. The guidance lists 27 specific factors, plus an ''other'' category allowing the applicant to select one additional locally-relevant factor not anticipated by the guidance. This approach produces a possible 30 points for the ''Health Disparities Factors'' section; combined with the possible 70 for ''Barriers and Access to Care'' section, allowing a possible 100 total points are possible. In current guidance, the threshold for having the application reviewed has been set at an NFA score of 70 out of the possible 100 total points.

Need for Assistance Worksheets and the Application Review Process

In accordance with the guidance, all applicants are required to complete an NFA Worksheet, identifying the NFA indicators they have selected from the options available and providing the data on these indicators for their proposed service area or target population. The Worksheet is reviewed by an Objective Review Committee (ORC), and only those applicants that achieve a score of 70 or higher out of the possible 100 points have the merits of their application evaluated by the ORC. To date, under the President's Initiative, HRSA has found that most applicants achieve the minimum of 70 NFA points required in the current process for consideration of their application. Furthermore, under the current application review process, only 10% of the total (100) possible points are allocated to the applicant's description of the need for additional primary care services in the community or target population to be served. Currently, application scores cluster at the high end of the scoring range, providing little discrimination among applications.

For these reasons, HRSA arranged for an external evaluation of the NFA criteria and the use of need factors in the overall application review process. (The evaluation was conducted by a team of HSR, Inc., and the University of North Carolina's Cecil G. Sheps Center for Health Services Research.) Key results of the evaluation analyses are presented below, followed by recommendations for proposed changes on which we are soliciting comments.

Current NFA Access Barriers—Frequency of Applicant Use; Scores Achieved

An analysis of applications received during FY 2004 indicated that, with respect to the eight ''Barriers and Access to Care'' indicators, 92% of applicants selected the indicator percent of target population below 200% poverty; 79% selected percent of target population uninsured; 78% selected shortage of primary care physicians; and 75% selected unemployment rate for the target population, while only 36% selected life expectancy of the target population and 34% selected travel time or distance. Language other than English and shortage of Public Housing were selected by 55% and 50% of the applicants respectively. Since applicants naturally chose the variables that gave them the highest scores, the average scores achieved on all of the ''Barriers and Access to Care'' indicators ranged from 12 to 14 for each, except for life expectancy, which had an average score of about 11. As a result, scores of 60 or more for the ''Barriers and Access to Care'' section were routinely obtained.

Current NFA Disparity Factors—Frequency of use by applicants. A similar analysis of the ''Health Disparity Factors'' selected by the same group of applicants showed that 8 indicators were selected by 50% or more of the applicants, and another 7 indicators were selected by one-third or more applicants. Twelve indicators were selected by 25% or fewer of the applicants. Ninety-five percent of the time a selected indicator received 3 points; only 5% of the time did an applicant receive 0 rather than 3 points for a disparity indicator supplied. Therefore, typically, at least 27 points were received for the ''Health Disparities Factors'' section. Combining at least 60 points for the ''Barriers and Access to Care'' section access barriers and 27 points for the ''Health Disparities Factors'' section, a typical application would get 87 points, easily exceeding the threshold of 70.

Distribution of All U.S. Counties on Current NFA Barrier Score Levels. To arrive at an understanding of why the scores for access barriers ran so high for most applications, an analysis of the scores that would be achieved by all 3,141 U.S. counties or county-equivalents was conducted. This analysis showed that, given the existing scales:

- On *Percent Below 200% of Poverty*, 665 of 3141 counties receive 14 points, another 993 receive 12 points, and 946 receive 10 points. The average county score is 11 points.
- On *Life Expectancy*, only 17 counties receive 14 points, but 601 counties receive 12 points, and 2,140 receive 10 points. The average county score is 10.1 points.
- On *Unemployment Rate*, the counties are distributed more evenly along the scoring scale, but only 2 counties receive zero points, and the average county score is 9.5 points.
- On *Percent Uninsured*, 1,609 counties receive 10 points, while 1,327 receive 8 points. The average county score is 9 points.
- By contrast, *Travel Time/Distance* shows better distinctions among counties using its existing scale; while 1,527 counties receive zero points, 950 receive 6 points, 294 receive 8 points, 112 receive 10 points, 52 receive 12 points and 51 receive 14 points. The average score is 3.5. HRSA is requesting feedback as to whether the scale should be adjusted to increase the numbers of counties getting 10, 12 or 14 points?
- In the case of *Language other than English,* the current scale seems to err in the direction of overly minimizing the points received: 2,410 counties receive zero points, and the average county score is only 1.8 points.
- On *Shortage of Primary Care Physicians,* 2,565 counties receive no points while 576 receive 14 points. This means that about one-sixth of counties are getting the maximum points, because they are wholly designated as HPSAs. This does not provide any flexibility in terms of the rest of the counties, some of which may be closer to eligibility for HPSA designation than others, while others contain part-county HPSAs.

Recommendations for Revising NFA Criteria/Worksheet. Based on the analysis described above, feedback from communities, applicants and several focus group sessions, HRSA is proposing the following changes to the NFA criteria and process:

- Require that three (3) major access barriers be measured for all applicants. These three would be (a) percent of the population with incomes below 200 percent of the poverty level, (b) percent of population uninsured, and (c) shortage of primary care physicians, the three barriers that are most frequently selected by applicants.
- Use the population-to-primary care physician ratio for the applicant's service area or target population as the measure of shortage of primary care physicians, rather than a simple yes/no response based on presence or absence of a HPSA designation, with a scale of the type used for the other access indicators.
- Allow the applicant to select two additional access barriers from the following five (5): Unemployment Rate of Population, Percent Linguistically Isolated Population (replacing language other than English), Standardized Mortality Rate for Population (replacing Life Expectancy Rate), Travel Time/Distance to Nearest Provider accepting Medicaid and/or Uninsured Patients, and (for Homeless or Public Housing applicants only) Waiting time for Public Housing.
- Choose the scale for each of the access indicators based on comparison to the national county distribution of that indicator. (The scales proposed to be used are displayed below.) No points would be awarded for a barrier value better than the national county median.
- Require that 5 ''core'' disparity factors closely related to health center primary care activities be measured for all applicants. The core indicators proposed are: asthma rate, diabetes rate, and cardiovascular disease rate among the population; one birth outcome measure (infant mortality rate or low live birthweight rate), and one mental health measure (depression rate or suicide rate) among population. [Of these factors, all but one (depression rate) were in the group of current indicators selected at least 33% of the time.]
- Allow 2 points for each core disparity factor on which the community value exceeds the national benchmark for that factor, which would be provided in HRSA's application guidance (rather than by the applicant). Allow an additional point if a higher ''severe'' benchmark, also specified in the guidance, is also exceeded. (Benchmarks proposed are appended below.)
- Have the applicant select 5 additional disparity factors from a list of 7 factors previously used that are closely related to health center primary care activities. The factors proposed are: immunization rate, hypertension rate, rate of respiratory infection, obesity, teenage pregnancy, substance abuse, and percent elderly population. Alternatively, the applicant may select 4 of these plus an ''other'' indicator specified by the applicant.
- Allow 2 points for each selected measure on which the community value exceeds the national benchmark. (Benchmarks proposed are appended below.) If ''other'' is selected, the applicant would need to both define the measure and suggest a benchmark for it as well. If the measure and the benchmark are accepted (or if the

measure is accepted but the benchmark is redefined), 2 points would be allowed if the benchmark is exceeded.

- Maximum possible total points for access barriers here is 75; and for disparities is 25 points, totaling 100 possible total points for NFA.
- A threshold of 50 points on this revised index is under consideration. Only those applicants with a NFA score of 50 or more would have their application reviewed by the ORC. HRSA is considering whether this threshold should be changed annually to maintain a certain ratio of number of applications reviewed to number of awards available.
- The NFA scores achieved could be factored into the application review process.

Relative Importance of Need as an Application Review Factor

The evaluation team also recommended that the relative need score from the NFA worksheet should be the basis for 20 percent of total application score, replacing the previous 10% for ''description of service area/community and target population.'' To accommodate this change, the evaluation team suggested reducing the proportion of the total application score now assigned to ''Governance'' from 10% to 5%, and reducing the proportion of total score assigned to ''Service Delivery Strategy and Model'' from 20% to 15%. However, HRSA has not taken a position on what new relative weighting might be most appropriate. Instead, by this notice, we are requesting public comments on this issue. Specifically, how should Need considerations be weighted in the application review process? What is the relative importance of Need versus such other factors as applicant Readiness to operate a health center, understanding of and connections to the local health care Environment, service delivery Strategy for addressing the needs of the community, plan for provision of specific required health Services, Organizational capabilities and expertise, Budget plan, and Governance? Rather than providing specific suggested percentages for weighting all these different factors, commenters are encouraged to isolate how Need should be weighted relative to all other factors, and whether this should be done by applying that weight to an objective index of relative community need such as that proposed above, or in some other manner.

BILLING CODE 4165–15–P

Proposed New Scales for NFA Access Barrier Indicators

1A. Core Barriers

For all 3 of the following indicators, give the most current value for an area which most closely approximates the proposed service area or target population.
For each indicator, give data source and year, and identify the reference area [by zip code(s), census tracts, or county] and/or population group used.
Scores will be assigned using the scales shown.

a. Population to Primary Care Physician Ratio

Ratio Range	Score
<1900	0
1900-1949	1
1950-1999	2
2000-2049	3
2050-2099	4
2100-2199	5
2200-2299	6
2300-2399	7
2400-2499	8
2500-2799	9
2800-3099	10
3100-3399	11
3400-4199	12
4200-4999	13
5000-5799	14
5800 or >5800	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____

Area Used:

b. Percent of Population Below 200 percent of poverty

Percent Range	Score
<40.5	0
40.5-43.5	3
43.5-46.5	6
46.5-50.0	9
50.0-55.0	12
>55.0	15

Value: _____
Data Source: _____

Data Year: _____
Area Used: _____ _____

c. Percent of Population Under Age 65 Uninsured

Percent Range	Score
<15.1	0
15.1-16.6	3
16.6-18.2	6
18.2-20.1	9
20.1-22.1	12
>22.1	15

Value: _____
Data Source: _____
Data Year: _____

Area Used:

Proposed New Scales for NFA Access Barrier Indicators, continued

1B. Other barriers

Applicants for funding under Section 330 (e) or (g): For **2 of the first 4 barriers listed below**, give the most current available value for an area/population group which most closely approximates the proposed service area and/or target population
Applicants for funding under Section 330 (h) or (i): For **2 of the 5 barriers listed below**, give the most current value for an area/population group which most closely approximates the proposed service area and/or target population.
For each indicator, give data source and year, and identify the reference area/population group used [by zip code(s), census tracts, or county].
Scores will be assigned using the scales shown.

d. Distance (miles) to nearest provider accepting New Medicaid patients and/or uninsured patients

Mileage Range	Score
<12	0
12-14	3
14-17	6
17-21	9
21-28	12
>28	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

e. Percent of Population Linguistically Isolated

Percentage Range	Score
<0.3	0
0.3-0.5	3
0.5-0.7	6
0.7-1.2	9
1.2-2.8	12
>2.8	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

f. Standardized Mortality Ratio

Ratio Range	Score
>74.3	0
73.8-74.3	3
73.2-73.8	6
72.5-73.2	9
71.4-72.5	12
<71.4	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

g. Unemployment Rate

Rate Range	Score
<5.0	0
5.0-5.7	3
5.7-6.6	6
6.6-7.5	9
7.5-9.3	12
>9.3	15

Value: _____ _____
Data Source: _____
Data Year: _____ _____
Area Used: _____

For 330(h) and (i) Applicants only:

h. Length of waiting time for public housing

Waiting Time Range	Score
< 90 days	0
3-6 months	3
6-12 months	6
12-18 months	9
18-24 months	12
> 24 months	15

Value: _____ _____
Data Source: _____ _____
Data Year: _____ _____
Area Used: _____ _____

Proposed Benchmarks for Disparities Indicators

2. Disparities

For ten disparity indicators, indicate the most current available value for an area or population group that most closely approximates the community, service area or target population proposed to be served. These will be compared with the benchmarks shown.

Include the data source, data year, and reference area or population group used.

All applicants must respond to the core disparities (1-5 below; two options each for 4 and 5.) 2 points are awarded if the area's value exceeds the benchmark X, and an additional point if the area's value exceeds the more severe threshold Y.

Choose any 5 of disparities 6-13; for each of these, 2 points are awarded if the benchmark X is exceeded.

	Benchmark (X)	Severe Threshold (Y)	Service Area Value	Source	Area	Year
Core Disparities (possible 2 or 3 Points each)						
1. Asthma	Prevalence: 7.6% of the population	Prevalence: 8.3% of the population				
2. Diabetes	26 diabetic deaths per 100,000 residents	35 diabetic deaths per 100,000 residents				
3. Cardiovascular	205 ischemic deaths per 100,000 residents	260 ischemic deaths per 100,000 residents				
4. Birth Outcomes						
a. Infant Mortality Rate (IMR) or	8 infant deaths per thousand live births	10 infant deaths per thousand live births				
b. Low Live Birthweight Rate (LBW)	7% of births are low birthweight births	8% of births are low birthweight births				
5. Mental Health						
a. Suicide Rate, or	12 per 100,000 residents	16 per 100,000 residents				
b. Depression Rate	TBD	TBD				
Other Disparities (possible 2 Points each)						
6. Teenage pregnancy rate	Pregnancies among 1.7% or more of females age 13-17					
7. Substance Abuse	TBD					
8. Immunization Rate	Less than 80% of children aged 19 to 35 months have received 4:3:1 vaccination series (4 DPT,3 polio, 1measles)					
9. Hypertension rate	25% of population have been told they have high blood pressure					
10. Rate of respiratory infection	More than 1.0 deaths per 10,000 due to pneumonia over 3 years					
11. Obesity	23% of adults classified as obese					
12. Percent of Population Aged 65+	15% of population					
13. Other*						

* Any "Other" indicator must be health related and specific to the target population to be served (as outlined in the application). Applicant must specify a suggested benchmark and provide the source of that benchmark

DATES: Please send comments no later than COB March 7, 2005. The comments should be addressed to Dr. Sam Shekar, Associate Administrator for Primary Health Care, Health Resources and Services Administration, Room 17–99,

5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Lynn Spector, Division of Health Center Development, Bureau of Primary Health Care, HRSA. Ms. Spector may be contacted by e-mail at *lspector@hrsa.gov* or via telephone at (301) 594–4300.

Dated: February 1, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–2215 Filed 2–1–05; 4:24 pm]

BILLING CODE 4165–15–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Physical Activity and Its Components In Relation To Plasma Inflammatory Markers of Cancer Risks Among Chinese Adults

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Physical Activity And Its Components In Relation To Plasma Inflammatory Markers Of Cancer Risks Among Chinese Adults.

Type of Information Collection Request: NEW.

Need and Use of Information Collection: The specific objectives of the current study are to: (1) Develop a comprehensive physical activity questionnaire that includes standardized questions about all types of physical activity (*e.g.*, recreational, household, occupational, and transportation), and all parameters of physical activity (*e.g.*, frequency, intensity; and duration in hours per week; (2) to assess the validity and reliability of this comprehensive physical activity questionnaire and the currently used baseline physical activity questionnaire in two existing study cohorts using objective measures of physical activity/physical fitness (activity monitors and step test), and; (3) to evaluate whether types and parameters of physical activity are associated with circulating levels of specific inflammatory markers that have been linked to cancer risk, independent of body mass and other potentially confounding variables. The specific markers are C-reactive protein (CRP), interleukin 6 (IL–6), and soluble tumor necrosis factor alpha (TNF-'').

The findings of this study will contribute to research in several important ways. They will allow the collection of objective physical activity measurements using activity monitors within a population with a wide range of between-person variation in physical activity; add to our understanding of the relationship of individual types of physical activity (*e.g.*, recreational, household, occupational, and transportation), and parameters of physical activity (*e.g.*, frequency, intensity, and duration in hours per week) to cancer outcomes; allow the use of physical activity information together with detailed, prospectively collected information regarding other lifestyle factors, such as diet and body mass, factors that are highly correlated with physical activity and also represent strong independent determinants of inflammatory mediator production, and; should the anticipated associations be found, the current study will likely stimulate future studies aimed at independently and jointly evaluating physical activity and chronic low-grade systemic inflammation in relation to cancer of several sites.

Frequency of Response: Once a month during a twelve-month period.

Affected Public: Approximately 600 men and women from a current cohort study among 75,000 women and 73,000 men and residing in Shanghai, China who agree to participate in this study.

Type of Respondents: Adult men and women aged 40 to 70 years old who are residents of Shanghai, China and current participants in another ongoing study. The annual reporting burden is as follows:

Estimated Number of Respondents: 600.

Estimates of Respondent Hour Burden and Annualized Cost to Respondents:

Type of respondents	Survey instruments per respondents	Number of participants	Frequency of response	Average burden hours per response	Total annual hour burden
Adults (40–70 yrs old)	Physical Activity Questionnaire	600	2	0.5	600
	7-Day Physical Activity Record	600	4	1.4	3360
	1-Week Physical Activity Recall	600	12	0.25	1800
TOTAL		600			5,760

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 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Michael F. Leitzmann, M.D., Dr. P.H., Nutritional Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, NIH, DHHS, 6120 Executive Blvd., EPS–MSC 7232, Bethesda, MD, 20892, U.S.A. or call non-toll-free number 301–402–3491 or E-mail your request, including your address to: *leitzmann@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.