

Weight Loss tablets, which contain chromium picolinate, claims that the product will cause weight loss, reduce cholesterol levels, control appetite, and increase metabolism. The Commission's complaint charges that the respondent did not possess and rely upon a reasonable basis that substantiated the claims at the time they were made.

In addition, the complaint alleges as false respondent's claim that these claims were based on competent and reliable scientific studies.

Lastly, the Commission's complaint charges that respondent represented, without a reasonable basis, that the testimonials or endorsements from consumers appearing in advertisements for its Nutra Trim brand products reflect the typical or ordinary experience of members of the public who use its cellulite reduction cream and weight loss tablets.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits the respondent from making unsubstantiated claims that its aminophylline-based cream can cause or contribute to cellulite reduction and fat loss and that its chromium picolinate weight loss tablets can cause or contribute to achieving body fat loss, weight loss, reduction in cholesterol levels, increase in metabolism, or appetite control. Part II of the proposed order prohibits the respondent from making any claims regarding the performance, benefits, efficacy, or safety of its products unless it has competent and reliable scientific evidence to substantiate such claims. Part III of the proposed order prohibits the respondent from making any misrepresentation regarding any test or study.

Part IV of the proposed order addresses claims made through endorsements or testimonials. Under Part IV, the respondent may make such representations if the respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representations; or the respondent must disclose either what the generally expected results would be for users of the advertised products, or the limited applicability of the endorser's experience to what consumers may generally expect to achieve. The proposed order's treatment of testimonial claims is in accordance with the Commission's "Guides Concerning Use of Endorsements and Testimonials in Advertising," 16 CFR 255.2(a).

Parts V and VI of the proposed order harmonize the requirements of the order with the requirements of the Nutrition Labeling and Education Act of 1990 and with Food and Drug Administration procedures.

The proposed order also requires the respondent to maintain advertising materials and materials relied upon to substantiate claims covered by the order; to provide a copy of the consent agreement to certain personnel in the company; to notify the Commission of any change in his employment; and to file one or more reports detailing compliance with the order.

Under Part XI, the order terminates 20 years from the date of issuance, except under certain specified conditions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Human Services Transportation Technical Assistance Project

AGENCY: The Assistant Secretary for Planning and Evaluation and the Director of the Office of Intergovernmental Affairs (IGA) of the Department of Health and Human Services (HHS).

ACTION: Requests for applications for technical assistance in the area of human services transportation from national organizations with a record of assisting rural and special transportation needs.

SUMMARY: This announcement solicits applications and describes the application process for the award of the cooperative agreement. It is the intent of HHS to fund one project which addresses the various task areas in this announcement. The project period will be for three years. However, an award will be funded only for the first year with funding for years two and three subject to the government's determination to continue the project.

DATES: The closing date for submittal of applications under this announcement is August 29, 1997.

ADDRESSES: Send application to Grants Officer, Department of Health and

Human Services, ASPE/IO, 200 Independence Avenue, SW., Room 405-A, Washington, DC 20201. Attn: Adrienne D.B. Little.

FOR FURTHER INFORMATION CONTACT: Technical Questions, Dianne L. McSwain, HHS/IGA, 200 Independence Avenue, SW., Room 630-F, Washington, DC 20201, Telephone: (202) 401-5926. Questions may be faxed to (202) 690-5672 (applications may not be faxed for submission). Application Instructions and Forms, Copies of applications should be requested from and submitted to: Grants Officer, Department of Health and Human Services, ASPE/IO, 200 Independence Avenue, SW., Room 405-A, Washington, DC 20201, phone (202) 690-8794. No faxes will be accepted. Questions concerning the preceding information should be submitted to the Grants Officer at the same address.

Eligible Applicants

Eligible applicants are national organizations or large institutions with a record of assisting rural and special transportation needs. Congress has indicated that the funded organization should have experience in administering a national toll-free hotline and electronic informational bulletin boards. It should regularly publish a national technical assistance periodical, maintain a national network of local and State affiliates, and have demonstrated experience in providing information and technical assistance on human services transportation to local agencies and programs.

Part I. Supplementary Information

Legislative Authority

The Transportation Coordination Technical Assistance Project cooperative agreement(s) are authorized by section 1110 of the Social Security Act (42 U.S.C. 1310) and awards will be made from funds appropriated under Public Law 104-208.

Project History and Purpose

In FY 1990, Congress authorized \$250,000 for the provision of technical assistance to human service transportation providers. This effort included the compilation of data on specific target populations, the development of mechanisms for dissemination of information, and the preparation of a report to the Secretary on the provision of transportation services to human service clients. For FYs 1991 through 1996, the Congress authorized \$500,000 for this effort, adding funding for specific technical assistance in the implementation of the requirements of the Americans with

Disabilities Act (ADA). For FY 1997, the Congress has again authorized \$500,000 for continued technical assistance in human services transportation.

The purpose of this announcement is to solicit applications for the provision of technical assistance to those organizations, agencies and individuals involved in the planning and provision of human services transportation to the clients of HHS-funded programs. This announcement represents a follow-on activity to the efforts funded in FYs 1991-1996.

It is the policy of HHS to coordinate related programs at the Federal level wherever possible and to promote maximum feasible coordination at the State and local level. Coordination and collaborative effort maximize the resources available to address specific needs. Reflecting this policy, HHS and the DOT have established the Joint DHHS/DOT Coordinating Council on Human Services Transportation (Coordinating Council) as a focal point for the effort to coordinate HHS and DOT resources for transportation of HHS program client populations. The goals of the Coordinating Council are as follows: (1) To achieve the most cost-effective use of Federal, State and local resources for specialized and human services transportation; (2) to encourage State and local governments to take a more active role in the management and coordination of programs supporting specialized and human services transportation; (3) to adopt administrative and management practices in the implementation of Federal programs which encourage coordination among service providers and increase access to specialized and human services transportation; (4) to share technical resources and information with recipients of Federal assistance and transportation providers; and (5) to encourage the most efficient system of providing services, including consideration of private sector providers and use of competitive bidding.

In support of these goals, HHS has identified the following objectives for the Human Services Transportation Technical Assistance Project: (1) To promote more efficient use of equipment, facilities, and staff resources at the State local level; (2) to provide information, technical data, and assistance to State and local agencies to improve management of transportation services and the acquisition of appropriate equipment and facilities and, more specifically, to assist states and localities in identifying needs, planning and implementing transportation alternatives for those individuals moving from welfare to

work. Applicants should reflect an understanding of these goals and objectives in their applications.

Available Funds

HHS intends to award one cooperative agreement resulting from this announcement. HHS anticipates awarding approximately \$400,000 through a cooperative agreement.

Period of Performance

The start-up date of the project will be September 15, 1997 for a project period of 36 months. However, an award will be funded only for the first year with funding for years two and three subject to the government's determination to continue the project.

Part II. Human Services Transportation Technical Assistance Project—Responsibilities of the Awardees and the Federal Government

Awardee Responsibilities

The Human Services Technical Assistance project requires the development and maintenance of mechanisms to provide information, technical assistance, and training to HHS human services transportation planners and providers on the efficient use of transit resources, equipment and facilities. Applicants should be aware of and be sensitive to the need to coordinate the activities herein with the activities of the Rural Transit Assistance Program (RTAP) funded through the Federal Transit Administration (FTA) of the Department of Transportation (DOT) and ongoing relevant transportation efforts by other federal departments. A listing of federal human services transportation funding sources can be found in the publication, "Building Mobility Partnerships" available through the National Transit Resource Center at 1-800-527-8279. Knowledge of the universe of federal efforts pertaining to the transportation of human services clients will be considered partially indicative of ability to perform the required tasks.

The following tasks are to be specifically addressed in the project narrative of the application. Applicants are encouraged to be innovative and to suggest additional or alternative approaches through subtasks that may improve the potential for successful completion of the task. However, applicants are cautioned to provide suggestions for additional subtasks judiciously with concern for the overall cost of the project. There will be no additional funds beyond those appropriated by Congress for this project.

Task I: Project Planning and Coordination

Task I entails the preparation of a detailed work plan of the activities proposed to meet the stated objectives of the project, including monthly meetings with the federal project staff, quarterly written progress reports and a final report due at the end of the project period. The work plan provides detailed descriptions of task activities, details on the intended staffing pattern and specific responsibilities within the project, specific time frames for the accomplishment of the activities in measurable terms and reflects consultation with the Federal Project Officer (FPO). In the second and third year, additional planning with the FPO should be reflected to allow for the annual minor project adjustments needed to keep the tasks relevant to consumer need.

In addition, it is anticipated that an evaluation of the effectiveness of the technical assistance efforts of the Community Transportation Assistance Project (CTAP) may be undertaken through the Human Service Transportation Research and Analysis project. The awardee might include possible activities to support and assist in this evaluation.

Task II: Development and Maintenance of Human Services Transportation Resource Center

Task II addresses the development and maintenance of a central repository of information and technical assistance materials for developing or improving coordinated transportation systems (hereafter known as the Resource Center). Access to the Resource Center should be available to State and local human service agencies, planning entities, government decision-makers and transportation service providers. The Resource Center will be the focal point for the ongoing collection and dissemination of information on issues of specific concern to human services transportation planners and providers as the issues evolve. A priority of the Resource Center will be the support of regional, State or local groups seeking to improve coordination of human services transportation as well as those groups emphasizing employment and child care transportation for low-income and welfare recipients.

The Resource Center collection of materials will represent the universe of reports, studies, and additional written and video materials that represent the current knowledge base in human services transportation. The Resource Center will include, at a minimum,

federal- and State-produced reports, technical assistance and training materials, federal human service transit-related legislation and regulations, training and technical assistance materials that will be developed through this effort, relevant research reports, and other relevant materials as identified by HHS, the Coordinating Council, or the awardee. All materials distributed through this project should carry the appropriate attribution in commonly accepted format. A thorough listing of proposed initial holdings for the Resource Center will be considered partially indicative of the ability to undertake this task. Although the awardee is encouraged to minimize costs by referral to other resources for acquisition of documents, a minimum of one copy of each identified referral piece will be maintained in the Resource Center for research purposes. In order to encourage students and practitioners to further the knowledge base, the Resource Center will be made available, within reasonable constraints, to individuals or organizations wishing to do research in the area of human services transportation.

Activities that might be undertaken to accomplish this task include: (1) Providing ready access to the technical assistance and information of the Center such as through the use of physical access, "hotlines" and the Internet; (2) developing a mechanism for periodic systematic searches of appropriate online information services to identify new materials; (3) maintaining ongoing relationships with the recognized individuals undertaking research in relevant fields in order to identify new work and to provide feedback on new issues to be explored; (4) identifying and maintaining contact with relevant transportation-related programs in colleges and universities; (5) developing and maintaining a calendar of the meetings, conferences and events of major organizations that would be of interest to the human services transportation field; and (6) developing procedures to ensure that organizations or individuals obtain requested materials or information in a timely manner. (Applicants are encouraged to disseminate information through links with other agencies rather than attempting to store and disseminate documents large quantities of documents);

Task III: Development and Coordination of a Resource Network of Knowledgeable Practitioners of Human Services Transportation

Task II represents the establishment and coordination of a network of

identified, certified practitioners in the field of human services transportation whose expertise can be made available to transportation planners or providers. Such expertise might be called upon for presentations at conferences or meetings, through telephone or written exchange, or on-site visits.

The following activities at a minimum, might be undertaken to complete this task; (1) Develop a set of criteria against which practitioners may be certified, (2) develop and implement a plan to identify practitioners for certification, (3) develop an automated database to manage the certified practitioner data, including name, contact information, specific expertise, title and description of current transportation position, and record of activity within the peer network; (4) develop a mechanism for screening requests for technical assistance which will identify the need for practitioner assistance and that assistance can be provided by telephone, in writing, or if an on-site visit is warranted, and (5) develop a process for documenting the practitioner contacts for inclusion in the Resource Center and to be summarized in the quarterly reports. Emphasis might be placed on the use of certified peers in ways to meet the most need.

Task IV: Disseminate Information on the Provision of Human Services Transportation

Task IV addresses the dissemination of the information compiled through the Resource Center activities, information accumulated under Task III, and information that the federal government deems necessary for distribution to the human services transportation network. The dissemination of information and materials relating to the implementing of the ADA transportation requirements, the effective coordination of transportation resources and successful approaches to employment and child care transportation for low-income individuals and welfare recipients are of priority under this task.

Project dissemination activities under Task IV will be coordinated with those of regional, State and other federal human services transportation coordination efforts to avoid duplication of efforts and to construct complementary and mutually beneficial activities. Under no circumstances should the awardee undertake the development of technical assistance or training information or materials that knowingly duplicate existing information or materials without prior written permission of the FPO. Whenever possible, partnering in the development of technical assistance

materials is desirable with the understanding that the use of project funds for such an effort must be clearly identifiable.

At a minimum the awardee would be expected to undertake the following activities in support of Task IV: (1) Identifying opportunities to disseminate information through the existing publications of relevant human services organizations on human services transportation issues (a minimum of 6 articles during the project period); (2) identifying and coordinating through the practitioner network requests for conveners and facilitator for regional, State and local-level human services organizations and forums (a minimum of 6 opportunities); (3) identifying, tracking and coordinating activities of other major national or regional human services organizations interested in human services transportation with activities planned under this project including identifying opportunities to participate in national or regional conferences (present at minimum of 5 human services meetings); (4) assist with the planning and facilitation of such regional conferences as may be held by HHS and FTA; (5) ensuring the availability of current information on the project resources and the Resource Center including the dissemination of a basic information package on the Resource Center through the major human services networks, at a minimum of once a year; (6) continue to disseminate the information on the transportation requirements of the ADA, as well as additional transportation requirements such as drug and alcohol testing and blood born pathogens handling, prepared summaries on these requirements as prepared during previous Human Services Transportation Training and Technical Assistance projects; (7) compile information on the transportation needs and experiences related to moving individuals from welfare to work, as well as the necessary link to child care, (8) compiling information on the usage of the Resource Center and dissemination activities, including but not limited to the data on the rate of use, kinds of inquiries, and types of requesting organizations, to be included in the monthly project meetings; and (9) indicate a process for screening requests for information and technical assistance which will identify the appropriate level and type of technical assistance, such as immediate telephone response, research and compilation of a written response, practitioner network assistance by telephone, in writing, or through an on-site visit.

Federal Government Cooperative Agreement Responsibilities

HHS or its representatives will provide: (1) Consultation and technical assistance in planning, operating, and evaluating the technical assistance activities of the project; (2) up-to-date information on federal government regulations identified as affecting the provision of transportation services to human service clients; (3) assistance in the evaluation of project effectiveness; (4) assistance in collaborating with appropriate State and local governmental entities in the performance of the project activities; (5) assistance in the identification of HHS information and technical assistance resources pertinent to the success of this project; and (6) assistance in the transfer of "successful practices" in the human services transportation to other Federal, State and local entities.

Part III. Application Preparation and Evaluation Criteria

This part contains information on the preparation of an application for submission under this announcement, the forms necessary for submission and the evaluation criteria under which the applications will be reviewed. Potential applicants should read this part carefully in conjunction with the information provided in Part II.

To ensure that organizations with the greatest capacity for providing quality services participate in this effort, applicants for funding under the announcement should reflect, in the program narrative section of the application, how they will be able to fulfill the responsibilities and requirements described in this section of the announcement. Applicants must address all the identified tasks. It is the intent of HHS to make an award sufficient to accomplish the entire scope of effort described in this announcement, if submissions of sufficient scope and quality are received to permit it.

The applicant should include: (1) A management plan, which sets forth how the project will be managed and who will be the key personnel involved, including a Gantt chart and other graphics which specifically display the management information provided in text; and (2) a budget plan, which specifically delineates the costs associated with the project. When the applicant chooses to suggest additional efforts to support a task, the cost of those additional efforts (not required by this announcement) should be separately identified. However, at no time will a proposed budget in excess of

\$400,000 for all the Tasks listed in the Announcement be considered for funding, unless the amount in excess of \$400,000 represents grantee cost-sharing.

Review Process and Funding Information

Applications that are submitted by the deadline date and which meet the screening criteria will be reviewed and scored competitively. The applications will be reviewed using the evaluation criteria listed below to score the applications. These review results will be a primary factor in funding decisions.

HHS reserves the option to discuss applications with other Federal agencies, Central or Regional Office staff, specialists, experts, States and the general public. Comments from these sources, along with those of the reviewers, will be considered in making funding decisions.

State Single Point of Contact (E.O. No. 12372)

The Department of Health and Human Services has determined that this program is not subject to Executive Order No. 12372, Intergovernmental Review of Federal Programs, because it is a program that is national in scope and the only impact on State and local governments would be through subgrants. Applicants are not required to seek intergovernmental review of their applications within the constraints of E.O. No. 12372.

Deadline for Submittal of Applications

The closing date for submittal of applications under this announcement is August 29, 1997. Applications must be postmarked or hand-delivered to the application receipt point no later than 5 p.m. on August 29, 1997.

Hand-delivered applications will be accepted Monday through Friday prior to and on August 29, 1997, during the working hours of 9 a.m. to 5 p.m. in the lobby of the Hubert H. Humphrey building located at 200 Independence Avenue, SW, in Washington, DC. When hand-delivering an application, call 690-8794 from the lobby for pick up. A staff person will be available to receive applications.

An application will be considered as meeting the deadline if it is either: (1) Received at, or hand-delivered to, the mailing address on or before August 29, 1997, or (2) Postmarked before midnight of the deadline date, August 29, 1997, and received in time to be considered during the competitive review process (within two weeks of the deadline date).

When mailing application packages, applicants are strongly advised to obtain

a legibly dated receipt from a commercial carrier (such as UPS, Federal Express, etc.) or from the U.S. Postal Service as proof of mailing by the deadline date. If there is a question as to when an application was mailed, applicants will be asked to provide proof of mailing by the deadline date. When proof is not provided, an application will not be considered for funding. Private metered postmarks are not acceptable as proof of timely mailing.

Applications which do not meet the August 29, 1997, deadline are considered late applications and will not be considered or reviewed in the current competition. HHS will send a letter to this effect to each late applicant.

HHS reserves the right to extend the deadline for all applications due to acts of God, such as floods, hurricanes or earthquakes; due to acts of war; if there is widespread disruption of the mail; or if HHS determines a deadline extension to be in the best interest of the Government. However, HHS will not waive or extend the deadline for any applicant unless the deadline is waived or extended for all applicants.

Application Requirements

Applicants are advised to read and follow this section very carefully. Applications which do not meet these initial requirements may not be considered or reviewed in the competition, and the applicant will be so informed. A complete and conforming application must meet the following requirements:

Eligible applicants are national organizations or large institutions with a record of assisting rural and special transportation needs. Congress has indicated that the funded organization should have experience in administering a national toll-free hotline and electronic informational bulletin boards. It should regularly publish a national technical assistance periodical, maintain a national network of local and State affiliates, and have demonstrated experience in providing information and technical assistance on human service transportation to local agencies and programs.

Application Forms

See section entitled "Components of a Complete Application." All of these documents must accompany the application package.

Maximum Length

No specific limit will be set for the length of the application. However, applications that are overly long and/or

contain superfluous material will be viewed as indicating an inefficient approach.

Evaluation Criteria

The evaluation criteria correspond to the outline for the development of the Program Narrative Statement of the application. Although not mandatory, it is strongly recommended that applications be prepared with the format indicated by this outline.

Applications which meet the initial requirements will be reviewed by a panel of at least three reviewers. Reviewers will determine the strengths and weaknesses of each application in terms of the evaluation criteria listed below, provide comments and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each section will be given in the review process.

1. *Understanding of the Effort.* The application discusses in detail the applicant's understanding of the need for the project, the background and evolution of the effort to coordinate human services transportation, the significant participants in the coordination effort, the universe of current federal activities, and the specific relevance of the proposed tasks to the identified need. The application relates the project to the goals and objectives described in the first section of this announcement. 20 points

2. *Project Approach.* The application outlines a sound and workable approach to the effort and details how the proposed tasks will be accomplished; cites factors which might accelerate or decelerate the work, giving acceptable reasons for taking this approach as opposed to others; describes and supports any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary collaborative involvements; and provides for projections of the accomplishments to be achieved. It lists the activities to be carried out in chronological order, showing a reasonable schedule of accomplishments and target dates.

To the extent applicable, the application identifies the kinds of data to be collected and/or maintained, and discusses the criteria to be used to evaluate the results and successes of the project. It describes the evaluation methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. The application also lists each organization, agency, consultant, or other key individuals or groups who

will work on the project, along with a description of the activities and nature of their effort or contribution. 35 points

3. *Staffing Utilization, Staff Background and Experience.* The application identifies the background of the principal project staff members. The name, address, training, educational background, and other qualifying experience are provided for the project director and the key project staff. Any staff to be added as a result of the award of this Cooperative agreement should be clearly delineated. The applicant provides assurance that the proposed staff will be available to work on the project effort upon award of the cooperative agreement. The principal author of the application is identified and that person's role in the project is identified. An assurance of timely notification of staff changes and/or revised staff responsibilities is requested. 20 points

4. *Organizational Experience.* The application identifies the qualifying experience of the organization to demonstrate the applicant's ability to effectively and efficiently administer this project. Congress has directed HHS to identify the applicant as a national organization or large institution with a record of assisting rural and special transportation needs. The organization should have experience in administering a national toll free assistance hotline and electronic informational bulletin boards. It should regularly publish a national technical assistance periodical, maintain a national network of local and state affiliates, and have demonstrated experience in providing information and technical assistance on human services transportation to local agencies and programs. Previous specific experience with work similar to the tasks proposed in clearly and specifically described.

The relationship between this project and other work planned, anticipated, or underway by the applicant is described, including a chart which lists all related Federal assistance received within the last five years. In the event a consortium of applicants is proposed, the project history of prior joint work should be provided. The previous Federal assistance is identified by project number, Federal agency, and grants or contracting officer. 25 points

Components of a Complete Application

A complete application consists of the following items in this order:

1. Application for Federal Assistance (Standard Form 424, REV 4-88);

2. Budget Information—Non-construction Programs (Standard Form 424A, REV 4-88);
3. Assurances—Non-construction Programs (Standard Form 424B, REV 4-88);
4. Table of Contents;
5. Budget justification for Section B—Budget Categories;
6. Proof of non-profit status, if appropriate;
7. Copy of the applicant's approved indirect cost rate agreement, if necessary;
8. Project Narrative Statement, organized in four sections addressing the following areas:
 - (a) Understanding of the Effort,
 - (b) Project Approach,
 - (c) Staffing Utilization, Staff Background, and Experience,
 - (d) Organizational Experience;
9. Any appendices/attachments;
10. Certification Regarding Drug-Free Workplace;
11. Certification Regarding Debarment, Suspension and Other Responsibility Matters;
12. Certification and, if necessary, Disclosure Regarding Lobbying;
13. Supplement to Section II—Key Personnel;
14. Application for Federal Assistance Checklist.

Dated: July 9, 1997.

David Garrison,

Principal Deputy Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Human Services Transportation Research and Analysis Project

AGENCY: The Assistant Secretary for Planning and Evaluation and the Director of the Office of Intergovernmental Affairs (IGA) of the Department of Health and Human Services (HHS).

ACTION: Request for applications for research and analysis in the area of human services transportation from national organizations with a record of successfully completing recognized research and analysis informing the field of human services transportation.

SUMMARY: This announcement solicits applications and describes the application process for the award of the cooperative agreement. It is the intent of HHS to fund one project which