

Food and Drug Administration

[Docket Nos. 91P-0186 and 93P-0306]

Proposed Warning Labels for Iron-Containing Products; FDA Report on Consumer Research; Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Consumer Research on Proposed Warning Labels for Iron-Containing Products," which describes the results of research conducted by the agency to evaluate consumer understanding of the proposed warning labels for iron-containing products. FDA is inviting comments on the findings in this report.

DATES: Written comments by July 24, 1995.

ADDRESSES: Submit written comments and requests for single copies of "Consumer Research on Proposed Warning Labels for Iron-Containing Products" to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Comments and requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. After the comment period shown above, copies of the document will be available at cost from the Freedom of Information Staff (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857. "Consumer Research on Proposed Warning Labels for Iron-Containing Products" and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Raymond E. Schucker, Center for Food Safety and Applied Nutrition (HFS-725), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5657.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 6, 1994 (59 FR 51030), FDA issued a proposal ("the initial proposal") on actions that it tentatively concluded were necessary to stop the recent epidemic of pediatric poisonings from over consumption of iron-containing products. In the **Federal Register** of February 16, 1995 (60 FR 8989), the agency issued a supplementary proposal to clarify

changes in its legal authority with the passage of the Dietary Supplement Health and Education Act (Pub. L. 103-417).

In the initial proposal, FDA announced that it may conduct focus group research to evaluate consumer understanding of the proposed warning messages and to ensure that the messages are not misleading. FDA has conducted this research. Consumers provided feedback as to their understanding of the proposed warnings and the degree to which the specific wording of the messages was believable, relevant, confusing, or irritating. Additional warning messages were created as a result of public comment on the proposed rule, and these messages were also evaluated in the focus groups.

FDA stated in the initial proposal that it would make a report of the results of this research available for public comment before it issued the final regulations. The research report is now available for public comment.

Dated: May 18, 1995.

David A. Kessler,*Commissioner of Food and Drugs.*

[FR Doc. 95-12605 Filed 5-22-95; 8:45 am]

BILLING CODE 4160-01-F**Public Health Service****Announcement of Availability of Funds for Family Planning Service Grants****AGENCY:** Public Health Service, HHS.**ACTION:** Notice.

SUMMARY: The Office of Population Affairs announces the availability of funds for FY 1996 family planning services grant projects under the authority of Title X of the Public Health Service Act (42 U.S.C. 300, *et seq.*) and solicits applications for competing grant awards to serve the areas and/or populations set out below. Only applications which propose to serve the populations and/or areas set out below will be accepted for review and possible funding.

OMB Catalog of Federal Domestic Assistance 93.217.

DATES: Application due dates vary. See Supplementary Information below.

ADDRESSES: Additional information may be obtained from and completed applications should be sent to the appropriate Regional Health Administrator at the address below:

Region I—(Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont): DHHS/PHS Region I, John F. Kennedy Federal

Building, Government Center, Room 1400, Boston, MA 02203

Region II—(New Jersey, New York, Puerto Rico, Virgin Islands): DHHS/PHS Region II, 26 Federal Plaza, Room 3337, New York, NY 10278

Region III—(Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, W. Virginia): DHHS/PHS Region III, 3535 Market Street, Philadelphia, PA 19101

Region IV—(Alabama, Florida, Georgia, Kentucky, Mississippi, N. Carolina, S. Carolina, Tennessee): DHHS/PHS Region IV, 101 Marietta Tower, Suite 1106, Atlanta, GA 30323

Region V—(Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin): DHHS/PHS Region V, 105 West Adams Street, 17th Floor, Chicago, IL 60603

Region VI—(Arkansas, Louisiana, New Mexico, Oklahoma, Texas): DHHS/PHS Region VI 1200 Main Tower Building, Room 1800, Dallas, TX 75202

Region VII—(Iowa, Kansas, Missouri, Nebraska): DHHS/PHS Region VII, 601 East 12th Street, 5th Fl., Kansas City, MO 64106

Region VIII—(Colorado, Montana, N. Dakota, S. Dakota, Utah, Wyoming): DHHS/PHS Region VIII, 1961 Stout Street, Denver, CO 80294

Region IX—(Arizona, California, Hawaii, Nevada, Commonwealth of the Northern Mariana Islands, American Samoa, Guam, Republic of Palau, Federated States of Micronesia, Republic of the Marshall Islands): DHHS/PHS Region IX, 50 United Nations Plaza, Room 327, San Francisco, CA 94102

Region X—(Alaska, Idaho, Oregon, Washington): DHHS/PHS Region X, Blanchard Plaza, 2201 Sixth Avenue, M/S RX-20, Seattle, WA 98121.

FOR FURTHER INFORMATION CONTACT:

Regional Grants Management Officers: Region I, Mary O'Brien—617/565-1482; Region II, Steven Wong—212/264-4496; Region III, Marty Bree—215/596-6653; Region IV, Wayne Cutchins—404/331-2597; Region V, Lawrence Poole—312/353-8700; Region VI, Joyce Bailey—214/767-3879; Region VII, Michael Rowland—816/426-2924; Region VIII, Susan A. Jaworowski—303/844-4461; Region IX, Ken Souza—415/556-8187; Region X, Jim Tipton—206/615/2473.

Regional Program Consultants for Family Planning: Region I, James Sliker—617/565-1452; Region II, Margaret Lee—212/264-2571; Region III, Elizabeth Reed—215/596-6686; Region IV, Christino Rodrigues—404/331-5254; Region V, George Hockenberry—312/535-1700; Region VI, Paul Smith—214/767-3072; Region

VII, Susan Moskosky—816/426-2924; Region VIII, John J. McCarthy, Jr.—303/844-5955; Region IX, James Hauser—415/556-7117; Region X, Karen Matsuda—206/615-2501.

SUPPLEMENTARY INFORMATION: Title X of the Public Health Service Act, 42 U.S.C. 300, *et seq.*, authorizes the Secretary of Health and Human Services (HHS) to award grants to public or private nonprofit entities to assist in the establishment and operation of voluntary family planning projects to provide a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents). The statute requires that, to the extent practicable, entities shall encourage family participation. Also, Title X funds may not be used in programs where abortion is a method of family planning. Implementing regulations appear at 42 CFR Part 59 Subpart A.

On February 5, 1993, HHS published at 58 FR 7462 an interim rule that suspends the 1988 Title X rules, pending the promulgation of new regulations. The principal effect of this action was to suspend the definitions of "family planning," "grantees," "prenatal care," "Title X," "Title X Program," and "Title X Project" presently found at 42 CFR 59.2 and 42 CFR 59.7-59.10. Proposed rules were also published at 58 FR 7464 on the same date. During the pendency of rulemaking, the compliance standards that were in effect prior to the issuance of the 1988 rule, including those set out in the 1981 Family Planning Guidelines, are being used to administer the program. Copies of the pre-1988 compliance standards are available from

the Regional Program Consultants listed above.

The Title X program has established these five priorities:

- (1) Increasing outreach to women not likely to seek services, including homeless persons, disabled persons, substance abusers and adolescents;
- (2) Expanding the comprehensiveness of reproductive health services, including STD and cancer screening and prevention, increased involvement of male partners, HIV prevention, education and counseling, and substance abuse screening and referral;
- (3) Serving adolescents, including more community education, emphasis on postponement of sexual activity, and more accessible provision of contraceptive counseling and contraception;
- (4) Eliminating disincentives to provide high-cost but highly effective contraceptives such as Norplant and Depo-Provera, serving high risk (and high-unit cost) clients, and providing nonrevenue-generating services such as community education and prevention services; and
- (5) Emphasizing training and retention of family planning nurse practitioners, particularly minority nurse practitioners and nurse practitioners serving disadvantaged and medically underserved communities.

These program priorities represent overriding goals which are being pursued to the extent that funding increases or increases in program efficiency allow. Some funding may be available to Title X grantees to improve and expand services.

The Administration's FY 1996 budget request for this program is \$198.9 million. This amount represents a three percent increase over the FY 1995 appropriation of \$193.3 million, of which \$179.6 million will be made available to Title X service grantees. Approximately 17 percent of the funds appropriated for FY 1996 and made available to Title X service grantees will be used for competing grants. The remaining funds will be used for non-competing continuation grants. This program announcement is subject to the appropriation of funds and is a contingency action being taken to ensure that, should funds become available for this purpose, they can be awarded in a timely fashion consistent with the needs of the program as well as to provide for the distribution of funds throughout the fiscal year. Since the precise funding levels for FY 1996 are uncertain at this point, the funding levels set out below are based on the FY 1994 appropriation level. However, it is expected that funding levels will be increased, if the appropriation for FY 1996 increases.

For FY 1995, the entire \$179.6 million will be allocated among the 10 DHHS regions, and will in turn be awarded to public and private non-profit agencies located within the regions. Each regional office is responsible for evaluating applications, establishing priorities, and setting funding levels according to criteria in 42 CFR 59.11.

This notice announces the availability of funds to provide family planning services in 16 States, the Navajo Reservation, and the Commonwealth of the Northern Mariana Islands. Competing grant applications are invited for the following areas:

Populations or areas to be served	Number of grants to be awarded	FY 1994 funding	Application due date	Grant funding date
Region I:				
Connecticut	1	\$1,486,000	9/1/95	1/1/96
Boston, MA	1	1,226,000	3/1/96	7/1/96/
Southeastern MA	1	712,000	9/1/95	1/1/96
Western MA	1	662,000	9/1/95	1/1/96
Central MA	1	501,000	9/1/95	1/1/96
Northeastern MA	1	746,000	3/1/96	7/1/96
Maine	1	1,089,000	3/1/96	7/1/96
New Hampshire	1	637,000	3/1/96	7/1/96
Rhode Island	1	415,000	3/1/96	7/1/96
Vermont	1	541,000	9/1/95	1/1/96
Region V:				
St. Paul, MN	1	235,000	9/1/95	1/1/96
Cleveland, OH	1	1,346,000	12/1/95	4/1/96
Region VI:				
Oklahoma	1	2,639,000	8/1/95	12/1/95
Texas	1	9,426,000	12/1/95	4/1/96
Region VII:				
Missouri	1	3,517,000	12/1/95	4/1/96
Nebraska	1	1,168,000	3/1/96	7/1/96

Populations or areas to be served	Number of grants to be awarded	FY 1994 funding	Application due date	Grant funding date
Region VIII:				
North Dakota	1	470,000	3/1/96	7/1/96
Utah	1	140,000	3/1/96	7/1/96
Region IX:				
Navajo Reservation-AZ	1	511,000	3/1/96	7/1/96
Hawaii	1	874,000	3/1/96	7/1/96
Clark County, NV	1	584,000	9/1/95	1/1/96
Commonwealth of the Northern Marianas Islands	1	67,000	9/1/95	1/1/96
Total	22	28,992,000

Applications must be postmarked or, if not sent by U.S. mail, received at the appropriate Grants Management Office no later than close of business on application due dates listed above. Private metered postmarks will not be acceptable as proof of timely mailing. Applications which are postmarked or, if not sent by U.S. mail, delivered to the appropriate Grants Management Office later than the application due date will be judged late and will not be accepted for review. (Applicants should request a legibly dated postmark from the U.S. Postal Service.) Applications which do not conform to the requirements of this program announcement or do not meet the applicable regulatory requirements at 42 CFR part 59, subpart A will not be accepted for review. Applicants will be so notified, and the applications will be returned.

Applications will be evaluated on the following criteria:

- (1) The number of patients and, in particular, the number of low-income patients to be served;
- (2) The extent to which family planning services are needed locally;
- (3) The relative need of the applicant;
- (4) The capacity of the applicant to make rapid and effective use of the Federal assistance;
- (5) The adequacy of the applicant's facilities and staff;
- (6) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and
- (7) The degree to which the project plan adequately provides for the requirements set forth in the Title X regulations

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS—led national activity for setting priority areas. This announcement is related to the priority areas of Family Planning. A midcourse review of the objectives is presently ongoing, and the

proposed revisions are contained in a draft report. A notice of Availability and Request for Comment on the Healthy People 2000 Midcourse Revisions was published in the **Federal Register** on October 3, 1994 (59 FR 50253). Requests for copies of the Draft for Public Review and Comment: Healthy People 2000 Midcourse Revisions can be faxed to (301) 594-5981 or mailed to: OFP/OPA, East-West Towers, Suite 200, 5600 Fishers Lane, Rockville, MD 20857. A new PHS report, Healthy People 2000 Midcourse Review and Revisions, featuring the final revisions and status report on progress in achieving targets for the year 2000, will be published in 1995.

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Application Requirements

Application kits (including the application form, PHS 5161—approved by OMB under control number 0937-0189) and technical assistance for preparing proposals are available from the regional offices. An application must contain: (1) A narrative description of the project and the manner in which the applicant intends to conduct it in order to carry out the regulations of the law and regulations; (2) a budget that includes an estimate of project income and costs, with justification for the amount of grant funds requested; (3) a description of the standards and qualifications that will be required for all personnel and facilities to be used by the project; and (4) such other pertinent information as may be required by the Secretary as specified in the application kit. In preparing an application, applications should respond to all applicable regulatory requirements.

Application Review and Evaluation

Each regional office is responsible for establishing its own review process. Applications must be submitted to the appropriate regional office at the address listed above. Staff are available to answer questions and provide limited technical assistance in the preparation of grant applications.

Grant Awards

Grant projects are generally approved for 3 to 5 years with an annual non-competitive review of a continuation application to obtain continued support. Non-competing continuation awards are subject to factors such as the project making satisfactory progress and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Federal Government.

Review Under Executive Order 12372

Applicants under this announcement are subject to the review requirements of Executive Order 12372, State Review of applications for Federal Financial Assistance, as implemented by 45 CFR part 100. As soon as possible, the applicant should discuss the project with the State Single Point of Contact (SPOC) for each State to be served. The application kit contains the currently available listing of the SPOCs which have elected to be informed of the submission of applications. For those States not represented on the listing, further inquiries should be made by the applicant regarding the submission to the Grants Management Office of the appropriate region. State Single Point of Contact comments must be received by the regional office 30 days prior to the funding date to be considered.

When final funding decisions have been made, each applicant will be notified by letter of the outcome of its application. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award,

which specifies to the grantee the amount of money awarded, the purposes of the grant, and terms and conditions of the grant award.

Dated: May 17, 1995.

Felicia H. Stewart,

Deputy Assistant Secretary for Population Affairs.

[FR Doc. 95-12556 Filed 5-22-95; 8:45 am]

BILLING CODE 4160-17-M

ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS

Proposed Criteria for Reviewing and Making Recommendations on Federal Mandates

ACTION: Notice of proposed criteria.

SUMMARY: The Advisory Commission on Intergovernmental Relations (ACIR) is soliciting public comments on its proposed criteria for investigating and reviewing existing federal mandates and formulating recommendations to modify, suspend, or terminate specific mandates on State, local, or Tribal governments.

DATES: Comments must be received by June 22, 1995.

ADDRESSES: Comments should be sent to Philip M. Dearborn, Director, Government Finance Research, ACIR, 800 K Street NW., Suite 450 South, Washington, DC 20575.

FOR FURTHER INFORMATION CONTACT: Philip Dearborn at 202/653-5538.

SUPPLEMENTARY INFORMATION: The Advisory Commission on Intergovernmental Relations (ACIR, 42 U.S.C. 4271) is charged in Sec. 302 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, 109 Stat. 67) with investigating and reviewing the role of Federal mandates in intergovernmental relations and formulating recommendations to modify, suspend, or terminate specific mandates on State, local, or Tribal governments.

Section 302 defines "Federal mandate" very broadly for the purposes of the ACIR review as "any provision in statute or regulation or any Federal court ruling that imposes an enforceable duty on State, local, or Tribal governments including a condition of Federal assistance or a duty arising from participation in a voluntary Federal program."

ACIR will select for in-depth review those Federal mandates generally recognized as creating significant concerns within the intergovernmental system. In accordance with Public Law 104-4, ACIR will give review priority to mandates that are subject to judicial

proceedings in Federal courts. To formulate its recommendations, ACIR will evaluate each mandate to determine the specific conditions causing concern.

The Commission will make the final decisions about which mandates it will review based on two types of criteria:

(1) Those that provide a basis for identifying mandates of significant concern; and

(2) Those that provide a basis for formulating recommendations to modify, suspend, or terminate specific mandates that are of concern.

Criteria for Identifying Mandates of Significant Concern

In general, Federal mandates will be selected for intensive review if they have one or more of the following characteristics:

1. The mandate requires State, local, or Tribal governments to expend substantial amounts to their own resources in a manner that significantly distorts their spending priorities. This addresses mandates that require more than incidental amounts of spending. It will not include all Federal mandates that require governments to spend money.

2. The mandate establishes terms or conditions for Federal assistance in a program or activity in which State, local, or Tribal governments have little discretion over whether or not to participate. This will include mandates in entitlements and discretionary programs. It will exclude conditions of grants in small categorical programs that are distributed on the basis of annual or periodic applications and that are received only by a limited number of governments.

3. The mandates abridges historic powers of State, local, or Tribal governments, the exercise of which would not adversely affect other jurisdictions. This will include mandates that have an impact on internal State, local, and Tribal government affairs related to issues not widely acknowledged as being of national concern and for which the absence of the mandate would not create adverse spillover effects.

4. The mandate imposes compliance requirements that make it difficult or impossible for State, local, and Tribal governments to implement. Implementation delays, issuance of court orders, or assessment of fines may be indicative of mandate requirements that go beyond State, local, or Tribal fiscal resources, or administrative or technological capacity, after reasonable efforts at compliance have been made.

5. The mandate has been the subject of widespread objections and

complaints by State and local governments and their representatives. This will include mandates that are based on problems of national scope, but are not federally funded.

Criteria for Formulating Recommendations

ACIR will investigate the specific characteristics of each mandate causing significant concern in order to formulate a recommendation to modify, suspend, or terminate the mandate. For purposes of formulating such recommendations, ACIR will focus on specific provisions in laws, regulations, or court orders.

When a mandate affects a State or local program that directly competes with a comparable private sector activity, ACIR will consider the effects on both the government and private sector in making its recommendation. ACIR also will consider (1) impacts of mandates on working men and women and (2) mandates for utilization of metric systems.

ACIR will investigate each mandate selected for intensive review to determine whether or not they have one or more of the following characteristics:

1. Federal Intrusion

- Requirements are not based on demonstrated national needs.
- Requirements are related to issues not widely recognized as national concerns or as being within the appropriate scope of Federal activities.
- Requirements are based on problems of national scope, but which State, local, or Tribal governments have been able or willing to solve effectively, either independently or through voluntary cooperation.
- Requirements are based on problems of national scope, but are not federally funded.

These mandates should be terminated or modified to express non-binding national guidelines. In some instances, the basis provision could be retained in Federal law, but compliance could be made voluntary.

2. Unnecessarily Rigid

- Provisions do not permit adjustments to the circumstances or needs of individual jurisdictions.
- Provisions restrict flexibility to use less costly or less onerous alternative procedures to achieve the goal of the mandate.
- Provisions do not allow governments to set implementation or compliance priorities and schedules, taking into account risk analysis, greatest benefit, or other factors.

These mandates should be modified to provide options, waivers, or exemptions, or be terminated.