

**AGENCY FOR INTERNATIONAL DEVELOPMENT**  
**PROJECT DATA SHEET**

1. TRANSACTION CODE **A**  
 A = Add  
 C = Change  
 D = Delete

Amendment Number **3**

DOCUMENT CODE **3**

2. COUNTRY/ENTITY  
 Worldwide

3. PROJECT NUMBER  
**931-0227**

4. BUREAU/OFFICE  
 S&T/N

5. PROJECT TITLE (maximum 40 characters)  
**Nutrition: Iron Deficiency Program Support**

6. PROJECT ASSISTANCE COMPLETION DATE (PACD)  
 MM DD YY  
**09 30 88**

7. ESTIMATED DATE OF OBLIGATION  
 (Under "B." below, enter 1, 2, 3, or 4)  
 A. Initial FY **76** B. Quarter  C. Final FY **88**

8. COSTS (\$000 OR EQUIVALENT \$1 = )

A. FUNDING SOURCE	FIRST FY			LIFE OF PROJECT		
	B. FX	C. L/C	D. Total	E. FX	F. L/C	G. Total
AID Appropriated Total						
(Grant)	( 3,933 )	( )	( )	( 3,933 )	( )	( 3,933 )
(Loan)	( )	( )	( )	( )	( )	( )
Other U.S.						
1.						
2.						
Host Country						
Other Donor(s)						
<b>TOTALS</b>	<b>3,933</b>			<b>3,933</b>		<b>3,933</b>

9. SCHEDULE OF AID FUNDING (\$000)

A. APPROPRIATION	B. PRIMARY PURPOSE CODE	C. PRIMARY TECH. CODE		D. OBLIGATIONS TO DATE		E. AMOUNT APPROVED THIS ACTION		F. LIFE OF PROJECT	
		1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan	1. Grant	2. Loan
(1) FN				2,216				2,983	
(2) HE				475				950	
(3)									
(4)									
<b>TOTALS</b>				<b>2,691</b>				<b>3,933</b>	

10. SECONDARY TECHNICAL CODES (maximum 6 codes of 3 positions each)

11. SECONDARY PURPOSE CODE

12. SPECIAL CONCERNS CODES (maximum 7 codes of 4 positions each)

A. Code

B. Amount

13. PROJECT PURPOSE (maximum 480 characters)

To assist developing countries design and implement programs to alleviate iron deficiency anemia.

14. SCHEDULED EVALUATIONS

Interim MM YY **07 85** Final MM YY

15. SOURCE/ORIGIN OF GOODS AND SERVICES

000  941  Local  Other (Specify)

16. AMENDMENTS/NATURE OF CHANGE PROPOSED (This is page 1 of a \_\_\_\_\_ page PP Amendment)

The authorized period of obligation is extended thru September 30, 1988.

17. APPROVED BY

Signature  
 Title **M. Peter McPherson**  
 Administrator  
 Agency for Int'l Development

Date Signed MM DD YY

18. DATE DOCUMENT RECEIVED IN AID/W, OR FOR AID/W DOCUMENTS, DATE OF DISTRIBUTION

MM DD YY

PROJECT AUTHORIZATION  
PART II

NAME OF COUNTRY:           Worldwide  
 NAME OF PROJECT:           Nutrition: Iron Deficiency Program Support  
 PROJECT NUMBER:           931-0227

1. Pursuant to Section 103 of the Foreign Assistance Act of 1961, as amended, the Iron Deficiency Program Support Project which is centrally funded was approved April 30, 1976, and amended on August 28, 1981 and December 19, 1985. That authorization is hereby amended as follows:

(a) The authorized period of obligation is extended from June 30, 1986 thru September 30, 1988.

2. The authorization cited above remains in force except as hereby amended.

*M. Peter McPherson*

M. Peter McPherson  
 Administrator  
 Agency for International  
 Development

Date June 30 1986

Clearances:

S&T/N, M. J. Forman	<u>MAJ</u>	Date	<u>5/30/86</u>
S&T/PO, G. Gower	<u>MS</u>	Date	<u>9/24/86</u>
S&T/FA, A. Bertrand	<u>YAB</u>	Date	<u>6/10/86</u>
SAA/S&T, N. Brady	<u>YAB</u>	Date	<u>6/13/86</u>
<i>S/M</i> GC, S. Tisa	<u>WJ</u>	Date	<u>6/11/86</u>
ES	<u>RCW</u>	Date	<u>6-26-86</u>

AGENCY FOR INTERNATIONAL DEVELOPMENT  
WASHINGTON, D.C. 20523

SENIOR ASSISTANT ADMINISTRATOR

JUN 13 1986

ACTION MEMORANDUM FOR THE ADMINISTRATOR

THRU: AA/PPC, Allison <sup>APV</sup>Herrick (Acting)  
FROM: SAA/S&T, N. C. Brady <sup>NCB</sup>  
SUBJECT: Iron Deficiency Program Support Project (931-0227)

Problem: Your approval is required for a two-year extension of the subject project because the cumulative life of project will exceed a total of ten years from the date of initial project obligation. The project will be extended through FY 1988. The current authorized funding level of \$3,933,000 will remain the same.

Discussion: In 1974, a mandate was given to the Agency to focus on iron deficiency anemia by the Secretary of State, Henry Kissinger, when he announced the U.S. Government's intention to combat this worldwide problem at the World Food Conference in Rome. Iron deficiency anemia is the most prevalent nutritional deficiency in the world today affecting an estimated one billion people, principally women of childbearing age and young children. Evidence shows that it impairs work capacity and performance. In severe cases iron deficiency anemia increases maternal morbidity and mortality and carries increased risk to the fetus. Anemia during pregnancy can result in reduced birth weight of offspring. An anemic child does not thrive and death may result because of the general susceptibility to other diseases.

The Iron Deficiency Program Support project was approved April 30, 1976 at an initial funding level of \$3,933,000 for a period from May, 1976 through FY 1981. The project extension from FY 1982 through FY 1985 was approved August 1981. The project was subsequently extended to June 30, 1986. The authorized life-of-project funding of \$3,933,000 has remained unchanged. At this time we recommend a two-year extension of the project which will permit the continuation of the current activities under a cooperative agreement with Kansas University Medical Center (KUMC) and a grant for the activities of the International Nutritional Anemia Consultative Group (INACG). The authorized funding level for the cooperative agreement to KUMC will be increased, and the INACG activities will continue. The life-of-project funding level of \$3,933,000, however, will remain the same.

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Accomplishments to date: The Agency's Iron Deficiency Program Support project is the most active and productive iron anemia program currently operating in the world. No other organization has developed the equivalent scientific and technical capability or involvement to combat iron deficiency anemia. During the last few years great strides have been made in efforts to better control this major nutritional problem.

Two novel products developed offer a potential breakthrough in combatting the problem: the new HBS (hydrodynamically balanced system) sustained release iron capsules and the unique chelator compound iron-EDTA (ethylene diamine tetra acetate):

HBS - The new HBS capsule, which slowly releases iron as it floats in the stomach, allows for increased iron to be absorbed. Because of HBS' long, slow release time, the incidence of iron side effects should be significantly reduced.

EDTA - Currently used bioavailable iron compounds often interact with substances in foods to give off flavor, color and odor. EDTA complexes enable iron to prevent these undesirable side effects without impairing the absorbability of iron.

The development of these products has been carried out through the collaborative efforts between A.I.D. supported research institutions and major international corporations, and coordination with other agencies such as the World Health Organization (WHO), the Pan American Health Organization (PAHO) and the United States Food and Drug Administration (USFDA). Since its inception, the project has encouraged industry's collaboration and, in return, the project has received private sector endorsement and support.

The project organized the International Nutritional Anemia Consultative Group (INACG) in 1976. This body is now recognized as the principal international forum on nutritional anemia. In addition to the international meetings it periodically convenes, the INACG issues monographs and papers on pertinent topics and functions to guide international activities aimed at reducing nutritional anemia in the world.

In 1976, funds were granted to the Institute of Nutrition of Central America and Panama (INCAP), a PAHO institute, to field study the use of iron-EDTA as an iron food fortificant in sugar. Results suggested that iron-EDTA is efficacious, safe and accepted by the population as a fortificant. Other researchers have studied iron-EDTA and have obtained similar results.

On May 15, 1986, the FDA stated "that reasonable levels of use of EDTA compounds in national food supplies are perfectly safe and reasonable".

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In 1978, AID awarded a grant to the Kansas University Medical Center (KUMC) to conduct studies in human subjects on the bioavailability of unique iron compounds and on the absorbability of iron when fed in conjunction with different foods and diets. Subsequently, the KUMC activities were expanded and continued under a cooperative agreement which was signed at a ceremony in Senator Robert Dole's office, September 1982, in which you participated. The cooperative agreement helped establish the International Center for the Control of Nutritional Anemia (ICCNA) at KUMC and has developed into the premier world center of its kind.

ICCNA contributions in the biomedical area have been significant. They include the improvement of methods and procedures for assessment of iron deficiency in ways which have: (a) reduced the time of laboratory analyses from four days to four hours, (b) improved the quality of reagent materials used in laboratory analysis, (c) improved significantly both the accuracy and precision of assessment, and (d) for the first time permitted a reliable assessment of iron intervention programs. The Center has worked closely with industry to clinically test and evaluate new iron pharmaceutical formulations. The new HBS sustained release iron capsule is one such innovative formulation which has the potential to be a major breakthrough in the management of iron deficiency anemia in women, particularly pregnant women. Moreover, the ICCNA has very recently reported success in using EDTA in the enhancement of iron bioavailability from Egyptian baladi (flat) bread. This finding is important because standard iron fortificants were essentially ineffective in baladi bread due to the high temperature baking procedures plus natural factors in the wheat flour that inhibit iron absorption. Potentials in iron food fortification are now far closer to being realized.

In addition, the ICCNA conducts an active training program in the new and improved techniques for LDC technical professionals at the managerial level. The ICCNA also technically assists governments and agencies in developing appropriate strategies for combatting iron deficiency anemia.

Scope of work of the proposed extension: Under the proposed extension KUMC will: (a) continue to improve laboratory methods and procedures for the assessment of iron deficiency status and detection of iron overload syndrome, (b) research iron bioavailability in human subjects, (c) train LDC technical professionals, (d) assist governments in planning strategies and programs to control anemia, (e) conduct field studies on the new HBS sustained release capsule, and (f) encourage governments to use iron-EDTA in fortification programs to combat anemia.

The INACG will continue to guide donor agencies and governments to develop programs that will reduce nutritional anemia. This August, INACG, with the participation of experts from the

clinical, scientific, and marketing areas representing industry, academia and donor agencies, will hold a workshop on the social marketing of programs to combat iron deficiency anemia. At the invitation of the government of Ecuador, INACG plans to convene a major international meeting of agencies, country and industry representatives and experts in Quito, Spring of 1987.

Funding: A Congressional Notification will be submitted for this extension. The FY 1986 OYB for S&T/Nutrition has \$200,000 to fund this activity.

Summary: The Iron Deficiency Program Support project has reached an important stage where newly developed products have the potential of making a significant contribution to controlling iron deficiency anemia. The proposed two-year extension will provide the time needed for further field testing and adoption of these new iron systems in national nutrition and health programs. The progress and outcome of the field testing during the next two years will greatly influence the direction and scope of work of a new, follow-on project.

Pursuant to A.I.D. Handbook 3, Chapter 5, Section E.2.b.(1)(d) the project authorization is reserved for the Administrator when the life of the project exceeds ten years from the date of initial obligation, which was FY 1976 for this project.

Recommendation: That you sign the attached Project Authorization to extend the final year of obligation to FY 1988.

- Attachments
- PAF and PDS
- Project Paper
- Cooperative Agreement with KUMC
- Grant with Nutrition Foundation (IVACG)

Clearances:

S&T/N, MJForman	<u>MJF</u>	Date	<u>5/30/86</u>
S&T/FA:ARBertrand	<u>AR</u>	Date	<u>6/10/86</u>
S&T/PO:GFGower	<u>GFG</u>	Date	<u>5 June 86</u>
PPC/PDPR:ARosenberg	<u>AR</u>	Date	<u>6/29</u>
GC:HFry	<u>HF</u>	Date	<u>6/4/86</u>
DAA/S&T:DBrennan	<u>DB</u>	Date	<u>6/12/86</u>

S&T/N:SKahn: jes:5/12/86:2119E-revised-5/23/86