

Time and Date: 9 a.m.–4 p.m., November 18, 1999.

Place: The Washington Court, 525 New Jersey Avenue, NW, Washington, DC 20001–1527.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The BSC, NIOSH is charged with providing advice to the Director, NIOSH on NIOSH research programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings, and disseminating results.

Matters to be Discussed: Agenda items include a report from the Director of NIOSH; Overview of FY99 NIOSH Grants Program; HearSafe 2000; NIOSH/NCI Diesel Study Update; NIOSH Strategic Surveillance Plan; Health Care Worker Research and Prevention Activities; Fire Fighter Initiative; and future activities of the Board.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION:

Bryan D. Hardin, Ph.D., Executive Secretary, BSC, NIOSH, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639–3773, fax 404/639–2170, e-mail: bdh1@cdc.gov.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 30, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–25961 Filed 10–5–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KB, the Administration on Children, Youth and Families (ACYF) (63 FR 58742), as last amended, November 2, 1998; Chapter KF, the Office of Child Support Enforcement

(OCSE) (63 FR 42050), as last amended, August 6, 1998; and Chapter KP, the Office of the Deputy Assistant Secretary for Administration (ODASA) (63 FR 69297), as last amended, December 16, 1998. This notice reflects the realignment of the formula, entitlement and block grants function within ACF.

These Chapters are amended as follows:

1. Chapter KB, Administration on Children, Youth and Families

A. Delete KB.10 Organization in its entirety and replace with the following:

KB.10 Organization. The Administration on Children, Youth and Families is headed by a Commissioner, who reports directly to the Assistant Secretary for Children and Families and consists of:

Office of the Commissioner (KBA)
Office of Management Services (KBA1)
Office of Grant Management (KBA2)
Office of State Systems (KBA3)
Head Start Bureau (KBC)
Program Operations Division (KBC1)
Program Support Division (KBC2)
Children's Bureau (KBD)
Office of Child Abuse and Neglect (KBD1)
Division of Policy (KBD2)
Division of Program Implementation (KBD3)
Division of Data, Research and Innovation (KBD4)
Division of Child Welfare Capacity Building (KBD5)
Family and Youth Services Bureau (KBE)
Child Care Bureau (KBG)
Immediate Office/Administration (KBG1)
Program Operations Division (KBG2)
Policy Division (KBG3)
Technical Assistance Division (KBG4)

B. Delete KB.20 Functions, Paragraph A, in its entirety and replace with the following:

KB.20 Functions. A. The Office of the Commissioner serves as principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other officials of the Department on the sound development of children, youth, and families. It provides executive direction and management strategy to ACYF components. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office.

In the immediate Office of the Commissioner, research and evaluation staff plan and manage major research, evaluation, and data analysis activities. Additional staff perform special projects for the Office of the Commissioner. In addition to the Immediate Office, the

Office of the Commissioner contains three organizational units. In support of the Commissioner and Deputy Commissioner and in consultation with ACYF programs the:

1. Office of Management Services manages the formulation and execution of the budgets for ACYF programs and for Federal administration; serves as the central control point for operational and long range planning; functions as Executive Secretariat for ACYF, including managing correspondence, correspondence systems, and electronic mail requests; reviews and manages clearance for program announcements for ACYF, the Administration for Native Americans, and the Administration on Developmental Disabilities; plans for coordinates the provision of staff development and training; provides support for ACYF's personnel administration, including staffing, employee and labor relations, performance management and employee recognition; manages procurement planning and provides technical assistance regarding procurement; plans for/oversees the discretionary grant paneling process; reviews and approves formula and entitlement programs for ACYF's bureaus and the Administration on Developmental Disabilities; manages ACYF-controlled space and facilities; performs manpower planning and administration; plans for, acquires, distributes and controls ACYF supplies; provides mail and messenger services; maintains duplicating, fax, and computer and computer peripheral equipment; supports and manages automation within ACYF; provides for health and safety; and oversees travel, time and attendance, and other administrative functions for ACYF.

The Office of Management Services also provides management and technical administration of formula and entitlement programs administered by the following ACF program offices: ACYF and ADD. It assures that all formula and entitlement awards conform with applicable statutes, regulations, and policies; computes grantee allocations; prepares formula and entitlement awards; ensures incorporation of necessary grant terms and conditions; monitors grantee expenditures; analyzes financial needs under formula and entitlement programs; provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ACF formula and entitlement grant systems and the Department's grant payment systems;

and performs audit resolution activities for formula and entitlement programs.

2. Office of Grants Management provides management and technical administration for discretionary grants for ACYF, the Administration on Developmental Disabilities (ADD), and the Administration for Native Americans (ANA); reviews, certifies and/or signs all discretionary grants; assures that all discretionary grants awarded by ACYF, ADD, and ANA conform with applicable statutes, regulations, and policies; computes grantee allocations, prepares discretionary grant awards, ensures, incorporation of necessary grant terms and conditions, and monitors grantee expenditures; analyzes financial needs under discretionary grant programs; provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ACYF, ADD, and ANA discretionary grant systems and the Department's grant payment systems; provides technical assistance to regional components on discretionary grant operations and technical grants management issues; and performs audit resolution activities for ACYF, ADD, and ANA discretionary grant programs. The Office of Grants Management coordinates and maintains liaison with the Department and other federal agencies on discretionary grants management and administration operational issues and activities.

3. Office of State Systems (OSS) approves advanced data processing planning documents; and reviews, assesses and inspects planning, design and operation of state management information systems. It directs state systems activities on partnership, collaborative efforts, and technical assistance activities. The Office provides leadership for provision of technical assistance to States on information systems projects; and advances the use of computer technology in the administration of child welfare and social services programs by States.

The Office reviews, analyzes, and approves/disapproves State requests for federal financial participation for automated systems development and activities which support the Child Care, Child Welfare, and Foster Care programs. It provides assistance to States in developing or modifying automation plans to conform to federal requirements. It monitors approved State systems development activities; conducts periodic reviews to assure

State compliance with regulatory requirements applicable to automated systems supported by Federal financial participation. It provides guidance to States on functional requirements for these automated information systems. IT promotes interstate transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems.

II. Chapter KF, Office of Child Support Enforcement

A. Delete KF.10 Organization in its entirety and replace with the following:

KF.10 Organization. The Office of Child Support Enforcement is headed by a Director and consists of:

Office of the Director (KFA)
Office of Central Office Operations (KFB)
Division of Audit (KFB1)
Division of Program Operations (KFB2)
Division of Policy and Planning (KFB3)
Division of Consumer Services (KFB4)
Division of State and Local Assistance (KFB5)
Office of Automation and Special Projects (KFC)
Division of Child Support Information Systems (KFC4)
Office of Grants Management (KFD)
Office of Mandatory Grants (KFG)

B. Delete KF.20 Functions, Paragraph A, in its entirety and replace with the following:

KF.20 Functions. A. Office of the Director. The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/Commissioner has day-to-day operational responsibility for Child Support Enforcement programs. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the Office of Central Office Operations, Office of Automation and Special Projects, Office of Grants Management and the Office of Mandatory Grants.

The Office is responsible for developing regulations, guidance and standards for States to observe in locating absent parents; establishing paternity and support obligations and enforcing support obligations; maintaining relationships with Department officials, other federal departments, State and local officials, and private organizations and individuals interested in the CSE program; coordinating and planning child support enforcement activities to maximize program effectiveness; and

approving all instructions, policies and publications issued by OCSE staff.

C. KF.20 Functions. Add paragraph E. Add the following to establish paragraph E.

E. Office of Mandatory Grants is headed by a Director who reports to the Deputy Director/Commissioner and provides management and technical administration of formula, entitlement and block grants administered by the following ACF program offices: OCSE; Office of Family Assistance (OFA); Office of Refugee Resettlement (ORR) and Office of Community Services (OCS). It assures that all formula, entitlement and block grant awards conform with applicable statutes, regulations, and policies; computes grantee allocations; prepares formula, entitlement and block grant awards; ensures incorporation of necessary grant terms and conditions; monitors grantee expenditures; analyzes financial needs under formula, entitlement and block grant programs; provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ACF formula, entitlement and block grant systems and the Department's grant payment systems; provides technical assistance to ACF program and regional components on formula, entitlement and block grant operations and technical grants management issues; and performs audit resolution activities for formula, entitlement and block grant programs. For OCSE and the other program offices served, provides liaison with the Department and other federal agencies on formula, entitlement and block grants management and administration operational issues and activities.

III. Chapter KP, Office of the Deputy Assistant Secretary for Administration

A. Delete KP.00 Mission in its entirety and replace with the following:

KP.00 Mission. The Deputy Assistant Secretary for Administration serves as principal advisor and counsel to the Assistant Secretary for Children and Families on all aspects of personnel administration and management, information resource management, financial, grants policy and procurement issues, staff development and training activities, organizational development and organizational analysis, administrative services and facilities management and state systems policy. Oversees the Executive Secretariat Office, the ACF Equal Employment Opportunity and Civil

Rights program and all special initiatives activities for ACF.

B. Delete KP.10 Organization in its entirety and replace with the following:

KP.10 Organization. The Office of the Deputy Assistant Secretary for Administration is headed by the Deputy Assistant Secretary who reports to the Assistant Secretary for Children and Families. The Office is organized as follows:

- Immediate Office of the Deputy Assistant Secretary for Administration (KPA)
- Office of Information Services (KPB)
- Office of Financial Service (KPC)
- Office of Acquisition Services and Organizational Development Initiatives (KPD)
- Office of Customer Service Administration (KPE)
- Office of State Systems Policy (KPF)
- Executive Secretariat Office (KPG)
- Office of Equal Employment Opportunity and Civil Rights (KPH)
- Office of Human Resource Management (KPJ)
- Office of Administrative Services and Facilities Management (KPL)

C. Delete KP.20 Functions, Paragraph A, in its entirety and replace with the following:

KP.20 Functions. A. Office of the Deputy Assistant Secretary for Administration (ODASA) directs and coordinates all administrative activities for the Administration for Children and Families. The Deputy Assistant Secretary for Administration serves as ACF's Chief Financial Officer (CFO); ACF's Chief Grants Management Officer; Federal Manager's Financial Integrity Act (FMFIA) Management Control Officer; Principal Information Resource Management Official serving as ACF's Chief Information Officer responsible for implementing the Information Technology Management Reform Act; and Reports Clearance Officer. The Deputy Assistant Secretary for Administration serves as the ACF liaison to the General Counsel and, as appropriate, initiates action in securing resolution of legal matters relating to management of the agency, and represents the Assistant Secretary on all administrative litigation matters.

The Deputy Assistant Secretary for Administration provides day-to-day executive leadership and direction to the Immediate Office of the Deputy Assistant Secretary for Administration, Executive Secretariat Office; Office of Administrative Services and Facilities Management; Office of Customer Service Administration; Office of Equal Employment Opportunity and Civil Rights; Office of Human Resource

Management; Office of Information Service; Office of Financial Services; Office of Acquisition Services and Organizational Development Initiatives; and Office of State Systems Policy. The Deputy Assistant Secretary for Administration represents the Assistant Secretary in HHS and with other Federal agencies and task forces in defining objectives and priorities, and in coordinating activities associated with reinvention and continuous improvement initiatives. The Immediate Office of the Deputy Assistant Secretary is responsible for overseeing ODASA's salaries and expenses budget. Provides direction to meet the human resource management needs within ODASA; coordinates with the office which handles ACF's human resources activities and the Department to provide ODASA staff with personnel services including position management, staffing, recruitment, employee and labor relations, employee assistance, payroll, staff development and training, and special hiring and placement programs; and maintains systems to track personnel actions to keep the Deputy Assistant Secretary for Administration and, as appropriate, the Directors of offices within ODSAS informed about the status of personnel actions, and employee programs and benefits. All ODASA personnel related issues, performance management activities and other administrative functions within ODASA are handled within this office.

D. Delete KP.20 Functions, Paragraph C, in its entirety and replace with the following:

C. The Office of Financial Services (OFS) supports the Deputy Assistant Secretary for Administration in fulfilling ACF's Chief Financial Officer, Management Control Officer, and Chief Grants Officer responsibilities including preparation of the CFO 5 Year Plan; performs audit oversight and liaison activities, including preparing reports to Congress, Office of the General Counsel and the Office of the Inspector General. OFS writes/interprets financial policy and researches appropriation law issues; oversees and coordinates ACF's Federal Manager's Financial Integrity Act (FMFIA) activities; performs debt management functions; develops and administers quality assurance, training and certification programs for grants management; and is responsible for the annual preparation and audit of ACF's financial statement requirements. It develops/interprets internal policies and procedures for OFS components and coordinates the management of ACF's interagency agreement activities.

OFS provides agency-wide guidance to program and regional office staff on grant related issues; including developing and interpreting financial and grants policy, coordinating strategic grants planning, facilitating policy advisory groups, and assuring consistent grant program announcements. OFS prepares, coordinates and disseminates action transmittals, information memoranda, and other policy guidance on financial and grants management issues; provides financial and grants administration training and technical assistance to ACF staff and grantees; directs and/or coordinates management initiatives to improve financial administration of ACF mandatory and discretionary grant programs. OFS also develops and delivers grants management training to ACF program and financial staff.

E. Delete KP.20 Functions, Paragraph D, in its entirety and replace with the following.

D. The Office of Acquisition Services and Organizational Development Initiatives (OASODI) provides leadership of assigned ACF special initiatives arising from Departmental, federal and non-federal directives to improve service delivery to customers and to enhance the employee work environment; develops policy and procedures for implementing organizational development activities; advises the Assistant Secretary, through the Deputy Assistant Secretary for Administration, on all aspects of organizational analysis including: planning for new organizational elements; and planning, organizing and performing studies, analyses and evaluations related to structural, functional and organizational issues, problems and policies to ensure organizational effectiveness; and provides centralized management and administration of acquisitions for ACF headquarters and regional components.

The Office of Acquisition Services and Organizational Development Initiatives serves as the ACF liaison with the Department and other federal and non-federal agencies to coordinate assigned cross-cutting ACF management improvement initiatives identified by the Department to improve service delivery to customers and to enhance the employee work environment. These assigned management initiatives include coordination and implementation of the HHS and ACF employee work life program; administrative guidance and support to the HHS and ACF Labor-Management Partnership Councils; coordination of Departmental and other employee surveys; and coordinating the

development of strategies and completing reports on progress of minority initiatives. The Office provides guidance to ACF program/staff/regional offices in developing strategies and implementation of initiatives; seeks counsel and advice from the Department and other federal agencies; and develops evaluation instruments to measure the success of ACF initiatives. The Office manages and coordinates designated incentive awards program. The Office also handles various federal initiatives.

The Office advises the Deputy Assistant Secretary for Administration on ACF organizational development activities; develops policies and procedures for implementing organizational development and other management improvement projects or programs; and applies tools and techniques such as re-engineering practices to design organizational development interventions aimed at improving ACF processes.

The Office provides technical assistance to ACF components on developing and finalizing reorganization proposals. As appropriate, the Office serves as liaison to the HHS Office of the Assistant Secretary for Management and Budget to coordinate organizational proposals requiring Secretarial approval; and prepares functional statements and official organizational charts. The Office administers ACF's system for review, approval, and documentation of delegations of authority.

The Office manages and administers all acquisitions for ACF headquarters and regional components; assures that all contracts awarded conform to applicable statutes, regulations and policies; develops ACF policies, procedures and instructions for the award and administration of all ACF acquisitions; reviews and interprets proposed HHS and OMB regulations; circulars and directives pertaining to acquisition management; solicits, negotiates, awards, modifies, terminates and close all acquisition issued by ACF; conducts the agency's Small and Disadvantaged Business Utilization Program; and provides training and technical assistance to program and staff components on significant acquisition policies and procedures. OASODI serves as the lead for ACF in coordination and liaison within ACF and with the Department, OMB, GSA and other federal agencies on procurement management issues and activities.

F. Delete KP.20 Functions, Paragraph E, in its entirety and replace with the following:

E. The Office of Customer Service Administration (OCSA) develops and

maintains a customer service plan for the Deputy Assistant Secretary for Administration (DASA) and conducts customer surveys for the DASA; facilitates and assists in developing and writing standard operating procedures for all components within the Office of the Deputy Assistant Secretary for Administration (ODASA); assists in office-specific training of ODASA staff; assists ODASA components with the provision of office-specific and functional training to program and regional offices; coordinates permanent and temporary teams formed within ODASA; develops and maintains ODASA staff directory and users' guide for ODASA services.

G. Delete KF.20 Functions, Paragraph F, in its entirety and replace with the following:

F. Office of State Systems Policy is responsible for developing departmental policies and procedures under which States obtain Federal financial participation in the cost of automated systems development to support programs funded under the Social Security Act. It serves as the departmental focal point and coordinator for the development and implementation of strategies and policies related to payment integrity, welfare systems integration, electronic benefit transfer and related initiatives and programs; and provides leadership and guidance to interagency work groups in these areas for the Department.

The Office provides policy guidance, management leadership and coordination regarding the optimum inter-operation of the multitude of complex Federal, State, local, tribal and private information technology systems used to carry out ACF programs. The management leadership and coordination is provided in the areas of systems assessments, systems design and planning, systems integration, data exchanges, information management, information security and electronic information exchanges. The Office leads ACF activities associated with business continuity contingency planning and with information technology partnership planning which occurs between ACF and its program partners.

H. Delete KF.20 Functions, Paragraph H, in its entirety and replace with the following:

H. Office of Equal Employment Opportunity and Civil Rights (OEEOCR) serves as the principal advisor through the Deputy Assistant Secretary for Administration to the Assistant Secretary on all aspects of the Equal Employment Opportunity and Civil Rights program.

Serves as the liaison between ACF and the HHS Office for Civil Rights. The Office directs and manages the ACF Equal Employment Opportunity and Civil Rights program in accordance with Equal Employment Opportunity Commission (EEOC) regulations and HHS guidelines. Immediate oversight is provided by a staff under the direction of the ACF EEO Officer. Plans, develops, and evaluates programs and procedures designed to identify and eliminate discrimination in employment, training, incentive awards, promotion and career opportunities. Responsible for implementing and evaluation a cost-effective, timely, and impartial system for processing individuals complaints of discrimination under Title VII of the Civil Rights Act of 1964, as amended. Provides information, guidance, advice, and technical assistance to ACF supervisors and managers on Affirmative Employment planning and other means of achieving parity and promoting work force diversity. Responsible for ensuring that ACF-conducted programs do not discriminate against recipients on the basis of race, color, national origin, age or disability. Monitors and implements civil rights compliance actions under Title VI, Section 504 of the Rehabilitation Act of 1973, as amended and the Age Discrimination Act of 1975, as amended. Implements the applicable provisions of the Americans with Disabilities Act of 1990.

I. Delete KF.20 Functions, Paragraph J, in its entirety and replace with the following:

J. The Office of Human Resource Management (OHRM) directs and manages the personnel operations and services for the Administration for Children and Families (ACF). Provides advice and assistance to ACT managers in their personnel management activities including workforce planning, recruitment, selection, position management, performance management, and designated performance and incentive awards. Provides a variety of service to ACF employees, including provision of employee assistance services and career, retirement and benefits counseling. Serves as ACF liaison to the Department on all payroll matters. Provides the following personnel administrative services: the exercise of appointing authority, position classification, awards authorization, personnel management evaluation, personnel action processing and recordkeeping. Manages the merit promotion, special hiring and placement programs. Provides leadership in directing and managing agency-wide staff development and training activities for ACF.

The Office provides leadership, oversight, and coordination for the planning, analysis, and development of human resource policies and programs. Serves as liaison between ACF, the Department, and the Office of Personnel Management. Provides technical advice and assistance on policy, legal and regulatory matters. Formulates and interprets policies pertaining to all areas related to personnel administration and management. Formulates and interprets new human resource programs and strategies.

Formulates and oversees the implementation of ACF-wide policies, regulations and procedures concerning all aspects of the Senior Executive Service (SES), and SES equivalent recruitment, staffing, position establishment, compensation, award, performance management and other related personnel areas. Manages the performance recognition systems and the responsibilities of the Executive Resources Board (ERB) and the Performance Review Board (PRB). Coordinates the Schedule C and Executive personnel activity with the Office of the Secretary. Is the focal point for data, reports, and analyses relating to SES, Schedule C and other executive personnel, such as those in Executive level positions.

Provides management advisory service on all labor management and employee relations issues. Plans and coordinates ACF-wide employee relations and labor relations activities, including the application and interpretation of the Federal Labor-Management Relations Program, collective bargaining agreements, disciplinary and adverse action regulations, and appeals. Pursues human relations innovations such as alternative dispute resolutions. Provides leadership in assuring the integrity, effectiveness and impartiality of ACF's alternative dispute resolution programs, grievances, and merit systems program. Participates in the formulation and implementation of policies, practices and matters affecting bargaining unit employees' working conditions by assuring management's compliance with the Federal Labor Relations Program (5 U.S.C. Chapter 71).

Administers ACF's personnel security responsibilities and ethics program. Coordinates the ethics program with the Department's Office of Special Counsel for Ethics.

The Office is responsible for the functional management of all program, common needs and management training in the agency, including policy development, guidance, and technical assistance and evaluation of aspects of

program, career, employee, supervisory, management and executive training. Provides leadership in managing/overseeing and monitoring the ACF Training Resource Center.

Dated: September 28, 1999.

Olivia A. Golden,

Assistant Secretary for Children and Families.

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BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-4235]

Agency Emergency Processing Under OMB Review; Survey of Manufacturing Practices in the Dietary Supplement Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is a survey of manufacturing practices of dietary supplement establishments. The objectives of the survey are to learn about the existing practices and to help the agency formulate a policy to ensure that dietary supplements are produced under conditions that will minimize safety problems resulting from manufacturing without imposing unnecessary costs to the industry. The survey will provide an understanding of the economic impact that any proposal to establish current good manufacturing practice (CGMP) regulations will have on both large and small firms in the dietary supplement industry.

DATES: Submit written comments on the collection of information by November 5, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION:

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. The information is essential to the agency's mission of protecting and promoting public health. The use of normal PRA clearance procedures would be likely to result in public harm; several recent illnesses and deaths are suspected to have resulted from the lack of CGMP for dietary supplements. The hazards associated with poor manufacturing practices include chemical and biological contaminants, ingredients not identified on the label, and highly variable amounts of ingredients. In order to assess the effects of a CGMP regulation, the agency needs more information about existing manufacturing practices.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Survey of Manufacturing Practices in the Dietary Supplement Industry

Under section 402(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2)), FDA may by regulation prescribe CGMP requirements for dietary supplements in order to ensure that dietary supplements are not adulterated during the manufacturing process. To gather information for use in developing CGMP regulations, FDA intends to conduct a survey of existing manufacturing practices for dietary supplements. Approximately 717 establishments will be selected from the universe of 2004 establishments in the Dietary Supplement Enhanced Establishment Database developed under contract by the Research Triangle Institute for the agency. The sample allocation is designed to yield 400 completed surveys. The survey will use a stratified systematic sample design with stratification by product type and