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.

[FR Doc. 99–26065 Filed 10–5–99; 8:45 am]

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

establishment size. The product types are vitamins and minerals, herbals and botanicals, herbal and botanical extracts, amino acids, proteins, animal extracts, tea-like products, concentrates/metabolites/constituents, and other dietary supplements. The survey is designed to determine the extent to which firm's operations use written procedures and maintain records to ensure that: (1) Personnel have the proper education, training and experience and are knowledgeable in disease control and other safety concerns; (2) buildings and facilities are maintained against contamination; (3) equipment is cleaned and sanitized; (4) quality control and laboratory operations determine that certificates of analysis are reliable and that identity and adulteration tests are conducted on raw materials and in-process formulations; (5) production and process controls use master and batch records as well as other records; (6) warehousing and distribution operations maintain records for forward and backward tracing of product; and (7) consumer complaints are handled and documented.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Computer Assisted Telephone Interview (CATI)	400	1	400	1.13	452

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's experience with conducting industry surveys.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25899 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

Name of Committee: Anti-Infective Drugs Advisory Committee.

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

Date and Time: The meeting will be held on October 20 and 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On the morning of October 20, 1999, the committee will discuss the development of antimicrobial drugs for the treatment of catheter-related bloodstream infections.

On the afternoon of October 20, 1999, the committee will discuss new drug applications (NDA's) 20–634 and 20–635, levofloxacin (Levaquin™, The R.W. Johnson Pharmaceutical Research Institute) for the treatment of community-acquired pneumonia due to penicillin-resistant *Streptococcal pneumoniae*.

On October 21, 1999, the committee will discuss NDA 21–085, moxifloxacin (Avelox™, Bayer Corp. Pharmaceutical Division), for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, skin and skin-structure infections, and acute sinusitis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1 p.m. and 1:30 p.m. on October 20, 1999, and between approximately 8 a.m. and 8:30 a.m. on October 21, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 1999, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 20, 1999, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: September 29, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–25970 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Round Table; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: ''Consumer Round Table—Risk Management in a Diverse Society.'' This meeting will provide an opportunity for consumers to engage in an open dialogue with senior officials on how FDA ensures drug safety and manages and communicates the risks and benefits of drug products.