1. Capacity (30 Points)

a. The extent to which the applicant describes the ability to deliver HIV, STD, or TB prevention and care programs and/or prenatal/obstetric/reproductive programs in accordance with GAA objectives.

b. The extent to which the applicant documents personnel staff positions, experience, training, and recruitment.

2. Proposed Program Plan (40 Points)

a. The appropriateness of proposed activities and interventions and extent to which they are targeted to address the priority needs;

b. The quality of the proposed objectives and extent to which they are specific, realistic, measurable, and time-phased;

c. Extent to which proposed activities, if well-executed, are capable of attaining project objectives; the likelihood that the proposed activities, interventions, and services will achieve the stated program goals and intent of this program announcement.

3. Collaboration (15 Points)

Extent to which the applicant organization can document a history of successful collaborations with the U.S. government and/or non-governmental organizations in carrying out projects of public health impact.

4. Evaluation (15 Points)

Quality of the plan for evaluating the proposed program activities and the likelihood that the evaluation will provide information that will lead to improvement of the program.

5. Budget (Not Scored)

Extent to which budget is reasonable, clearly justified, consistent with the intended use of the funds, and allowable. All budget categories should be itemized.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Annual progress report
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

For descriptions of the following Other Requirements, see Attachment II. Some of the more complex requirements have some additional information provided below:

AR–1 Human Subjects Requirements
AR–4 HIV/AIDS Confidentiality Provisions
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–12 Lobbying Restrictions
AR–14 Accounting System Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 307 of the Public Health Service Act, 42 U.S.C. 241 and 2421, and section 104 of the Foreign Assistance Act of 1961, 22 U.S.C. 2151b. The Catalog of Federal Domestic Assistance Number is 93.939, HIV Prevention Activities—Nongovernmental Organization.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—http://www.cdc.gov. Scroll down the page, click on ''Funding'', then ''Grants and Cooperative Agreements.''

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888 472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Dorimar Rosado, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, MailStop E–15, Atlanta, GA 30341–4146, Telephone (770) 488–2736, E-mail address: dpr7@cdc.gov.

For program technical assistance, contact: Leo Weakland, Deputy Coordinator, Global AIDS Activity (GAA), National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, M/S E–07, Atlanta, GA 30333, Telephone number (404) 639–8016, Email address: lfw0@cdc.gov.

Dated: July 5, 2000.

Ron Van Duyne,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–17446 Filed 7–10–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following Advisory Committee meeting.

Name: Advisory Committee to the Director, CDC.

Time and Date: 8:30 a.m.–4 p.m., August 4, 2000.

Place: The Sheraton Colony Square Hotel, 188 14th Street, N.E., Atlanta, Georgia 30361.

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

Purpose: The committee will anticipate, identify, and propose solutions to strategic and broad issues facing CDC.

Matters to Be Discussed: Agenda items will include updates from Dr. Jeffrey P. Koplan, Director, CDC regarding the current CDC Director's priorities with a focus on selected CDC programs including Immunizations, Prevention Research, and Tobacco.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Kathy Cahill, Executive Secretary, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE, M/S D–24, Atlanta, Georgia 30333. Telephone 404/639–7060.

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: July 3, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–17448 Filed 7–10–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00P–1280]

Medical Devices; Exemptions From Premarket Notification; Class II Devices: Triiodothyronine Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for the total triiodothyronine test system class II device (special controls). FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by August 10, 2000.

ADDRESSES: Submit written comments on this notice to the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of the FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). In the **Federal Register** of November 3, 1998 (63 FR 59222), FDA published a final rule codifying these exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for class II devices:

Abbott Laboratories, *Total triiodothyronine test system*, 21 CFR 862.1710.

IV. Comments

Interested persons may submit to the Docket Management Branch (address above) written comments regarding this petition by August 10, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 28, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–17389 Filed 7–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00N–0504]

Egg Safety; Current Thinking Papers on Egg Safety National Standards; Notice of Availability; Public Meeting

[Docket No. 98–045N4]

AGENCIES: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) and the Food