DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

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 meeting of the aforementioned committee:

Times and Dates: 8 a.m.–6 p.m., October 24, 2007; 8 a.m.–5 p.m., October 25, 2007

Place: CDC, Tom Harkin Global Communications Center, 1600 Clifton Road, NE., Building 19, Kent ''Oz'' Nelson Auditorium, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include discussions on Influenza Vaccines; Meningococcal Conjugate Vaccine; Childhood and Adolescent Immunization Schedule—2007; Immunization Schedule for HIV-Infected Adults; Pediatric Use of Pneumococcal Vaccines; Updates on Combination Vaccines, Vaccine Supply and Hepatitis B Vaccine; Immunization Safety Office; HPV Vaccines; Rotavirus Vaccine; and departmental updates. There may be possible VFC voting on the Influenza and Meningococcal Vaccines.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Tonica Gleaton, Immunization Services Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., (E–05), Atlanta, Georgia 30333, Telephone (404) 639–8836, Fax (404) 639–8905.

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 CDC and the Agency for Toxic Substance and Disease Registry.

Dated: September 26, 2007.

Elaine L. Baker,

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

[FR Doc. E7–19393 Filed 10–1–07; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Coordinating Center for Infectious Diseases (CCID)

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 meeting of the aforementioned committee.

Times and Dates: 9 a.m.–5 p.m., October 31, 2007; 8:30 a.m.–3:30 p.m., November 1, 2007

Place: CDC, Building 19, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Board of Scientific Counselors, Coordinating Center for Infectious Diseases (CCID), provides advice and guidance to the Director, CDC, and Director, CCID, in the following areas: program goals and objectives, strategies, program organization and resources for infectious disease prevention and control, and program priorities.

Matters To Be Discussed: Agenda items will include:

1. Breakout Group Discussions:

A. Laboratory Preparedness and Sustainability, National Center for Prevention, Detection, and Control of Infectious Diseases.

B. Influenza Diagnostics Program, National Center for Immunization, and Respiratory Diseases (NCIRD).

C. Immunization Assessment and Coverage, NCIRD.

D. Strategic Surveillance, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

E. Infectious Disease Ecology, National Center for Zoonotic, Vector-Borne, and Enteric Diseases.

2. Surveillance Systems.

3. CCID Updates.

4. Budget Updates.

Other agenda items include announcements and introductions, follow-up on actions recommended by the Board from March 2007, consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

Contact Person for More Information: Harriette Lynch, Office of the Director, NCID, CDC, Mailstop A–45, 1600 Clifton Road, NE., Atlanta, Georgia 30333, e-mail: *HLynch@cdc.gov,* telephone 404/639–4035.

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 26, 2007.

Elaine L. Baker,

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

[FR Doc. E7–19403 Filed 10–1–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0014]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Electronic Submission Using Food and Drug Administration Forms 3503 and 3504

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Electronic Submission Using Food and Drug Administration Forms 3503 and 3504'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 25, 2007 (72 FR 20553), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0016. The approval expires on August 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19350 Filed 10–1–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0359]

Agency Emergency Processing Under OMB Review; Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification Form FDA 3602A

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 concerns a new FDA foreign small business qualification certification form that will allow a foreign business to qualify as a ''small business'' and pay certain medical device user fees at reduced rates.

DATES: Fax written comments on the collection of information by October 5, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mail to baguilar@omb.eop.gov. All comments should be identified with the OMB Control Number 0910–NEW and the title ''Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A; (21 U.S.C. 379j); Emergency Request.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: FDA is requesting 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 Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), which expires September 30, 2007, amended section 738 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U. S.C. 379j) to provide FDA with new responsibilities and resources to keep up with the rapidly growing device industry and changing medical device technology. Congress recently passed an omnibus FDA bill that includes the ''Medical Device User Fee Amendments of 2007,'' (the 2007 Amendments), which will reauthorize medical device user fees for fiscal years 2008 through 2012 and will make significant changes to the medical device user fee provisions of the act. The 2007 Amendments will provide a new way for a foreign business to qualify as a ''small business'' eligible to pay a significantly-lower fee when a medical device user fee must be paid. The user fee provisions of the 2007 Amendments provide for an October 1, 2007, effective date, and FDA expects foreign businesses will want to request small business status immediately upon enactment.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Medical Device User Fee Amendments of 2007; Foreign Small Business Qualification Certification, Form FDA 3602A; (21 U.S.C.379j); Emergency Request

Congress recently passed an omnibus FDA bill that includes the 2007 Amendments, which will reauthorize medical device user fees for fiscal years 2008 through 2012 and will makes significant changes to the medical device user fee provisions of the act. The 2007Amendments will provide a new way for a foreign business to qualify as a ''small business'' eligible to pay a significantly-lower fee when a medical device user fee must be paid.

Under existing law, the only way a business could qualify as a ''small business'' was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Since many foreign businesses have not, and cannot, filed a Federal (U.S.) income tax return, this requirement has effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, have objected.

In lieu of a Federal income tax return, the 2007 Amendments will allow a foreign business to qualify as a ''small business'' by submitting a certification form, from its ''national taxing authority,'' the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification'' must:

- Be in English;
- Be from the national taxing authority of the country in which the business is headquartered;
- Provide the business's gross receipts or sales for the most recent year, in both the local currency and in United States dollars, and the exchange rate used in converting local currency to U.S. dollars;
- Provide the dates during which the reported receipts or sales were collected; and
- Bear the official seal of the national taxing authority.

The new FDA Form 3602A, '' FY 2008 MDUFMA Foreign Small Business Qualification Certification,'' will collect the information required by the statute and will allow a foreign business to qualify for the same small business benefits as a domestic U.S. small business. The user fee provisions of 2007 Amendments provide for an October 1, 2007, effective date, and FDA expects foreign businesses will want to request small business status immediately upon enactment.

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