Dated: December 23, 2002.

**John R. Moore,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02–32958 Filed 12–27–02; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Vaccine Advisory Committee, Subcommittee on Future Vaccines, Subcommittee on Immunization Coverage, and Subcommittee on Vaccine Safety and Communication Meetings

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 Federal advisory committee meetings.

*Name:* National Vaccine Advisory Committee (NVAC).

*Times and Dates:* 9 a.m.–5 p.m., February 4, 2003; 8:30 a.m.–3 p.m., February 5, 2003.

*Place:* Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue, SW., Washington, DC 20201.

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

*Notice:* In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey Building by non-government employees. Thus, persons without a government identification card should plan to arrive at the building each day either between 8 a.m. and 8:30 a.m. or 12:30 p.m. and 1 p.m. Entrance to the meeting at other times during the day cannot be assured.

*Purpose:* This committee advises and makes recommendations to the Director of the National Vaccine Program on matters related to the Program responsibilities.

*Matters to be Discussed:* Agenda items will include: a report from the National Vaccine Program Office (NVPO) and the Interagency Vaccine Workgroup; a report from the Assistant Secretary for Health; a discussion of homeland security and the role of vaccines; an update on the status of the smallpox vaccination program; an update on vaccine supply; an update on compensation for vaccine administration: Centers for Medicare and Medicaid Services Ruling; a report from the NVAC Workgroup on Public Health Options for Implementing Immunization Requirements; a report from the Institute of Medicine (IOM) regarding SV–40; a discussion of the Department of Health and Human Services global health agenda; an update on polio eradication and polio laboratory containment; a discussion of the Homeland Security Act; reports from the Vaccine Safety and Communication Subcommittee, Immunization Coverage Subcommittee, and the Future Vaccines Subcommittee; and, reports from the Advisory Commission on Childhood Vaccines/Division of Vaccine Injury Compensation, Vaccine Related Biological Products Advisory Committee/Food and Drug Administration, Advisory Committee on Immunization Practices/National Immunization Program/National Center for Infectious Diseases.

*Name:* Subcommittee on Future Vaccines.

*Time and Date:* 3:15 p.m.–5 p.m., February 4, 2003.

*Place:* Hubert H. Humphrey Building, Room 405A, 200 Independence Avenue, SW., Washington, DC 20201.

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

*Purpose:* This subcommittee develops policy options and guides national activities that lead to accelerated development, licensure, and the best use of new vaccines in the simplest possible immunization schedules.

*Matters to be Discussed:* Agenda items include an update on planning for a workshop on Pneumococcal Disease Prevention in Adults; discussion of pertussis vaccine strategies; and, a discussion of future vaccine technologies.

*Name:* Subcommittee on Immunization Coverage.

*Time and Date:* 3:15 p.m.–5 p.m., February 4, 2003.

*Place:* Hubert H. Humphrey Building, Room 705A, 200 Independence Avenue, SW., Washington, DC 20201.

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

*Purpose:* This subcommittee will identify and propose solutions that provide a multifaceted and holistic approach to reducing barriers that result in low immunization coverage for children.

*Matters to be Discussed:* Agenda items will include an update on Publication of Adult and Pediatric Standards; presentation of the draft report from the Workgroup on Public Health Options for Implementing Immunization Recommendations; an update on the status of the IOM report on vaccine financing; a discussion of creative methods for funding immunization registries; a review of adolescent coverage rates; and, areas of focus for unmet needs funding.

*Name:* Subcommittee on Vaccine Safety and Communication.

*Time and Date:* 3:15 p.m.–5 p.m., February 4, 2003.

*Place:* Hubert H. Humphrey Building, Room 425A, 200 Independence Avenue, SW., Washington, DC 20201.

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

*Purpose:* This subcommittee reviews issues relevant to vaccine safety and adverse reactions to vaccines.

*Matters to be Discussed:* Items to be discussed include a report from the IOM Vaccine Safety Review Committee on future activities and risk communication recommendations; a follow-up of the NVPO Risk Communication Workshop; and, a discussion of the smallpox vaccine communication plan.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Gloria Sagar, Committee Management Specialist, NVPO, CDC, 4700 Buford Highway M/S K–77, Chamblee, Georgia 30341, telephone 770/488–2040.

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: December 20, 2002.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 02–32864 Filed 12–27–02; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0077]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Emergency Medical Device Shortage Program Survey

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's emergency medical device shortage program survey. In the **Federal Register** of May 22, 2002 (67 FR 36008), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910–0491). Because this was an emergency approval that expired on October 31, 2002, FDA in this notice is following the normal PRA clearance procedures by issuing this notice.

**DATES:** Submit written or electronic comments on the collection of information by February 28, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.accessdata.fda.gov/scripts/oc/*

*dockets/edockethome.cfm*. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, 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.

**Emergency Medical Device Shortage Program Survey (OMB Control Number 0910–0491)—Reinstatement**

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively FDA's mission. Section 510 of the act (21 U.S.C. 360) requires that domestic establishments engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of medical devices intended for human use and commercial distribution register their establishments and list the devices they manufacture with FDA. Section 522 of the act (21 U.S.C. 360(l)) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. These sections of the act enable FDA to enhance consumer protection from risks associated with medical devices usage that are not foreseen or apparent during the premarket notification and review process.

Subsequent to the events of September 11, 2001, FDA began planning for handling device-related issues related to counter-terrorism. One of the activities related to planning for addressing terrorism-related medical device shortages is that FDA, working with medical experts and medical device industry organizations, developed a medical device formulary that identifies which medical devices would be needed in responding to terrorist incidents. The National Pharmaceutical Stockpile Program managed by the Centers for Disease Control (CDC) appears to have not given adequate consideration to medical devices. Therefore, FDA has developed a plan to ensure adequate availability of medical devices in case of terrorist incidents.

Most particularly, consumable supplies or disposable devices are supplied through large regional distributors. Adequate supplies should be available through these existing commercial supply chains. Problems in supplying these items will be due to logistics. In an emergency, FDA plans to ensure adequate availability of these types of devices by working with industry/distributor organizations. These organizations have actively pursued working relationships with appropriate government agencies to facilitate adequate response in emergency situations.

However, there are more sophisticated or specialized devices, for example, ventilators, defibrillators, portable x-ray machines, that are sold directly by the manufacturer, that are not through independent distributors. For these devices, FDA plans to maintain a database of device manufacturers so that specific contact information can be supplied to Emergency Response personnel as needed. FDA has identified 17 of these devices and has identified 205 manufacturers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Telephone survey | 250 | 1 | 250 | .5 | 125 |
| Total | | | | | 125 |

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal FDA experience and estimates.

The total number of medical device manufacturers regulated by FDA is estimated to be 70,000. Because most of the medical devices which might be needed in a terrorist attack are available through regular commercial channels, FDA focused this collection of information on the 250 manufacturers who manufacture 17 medical devices. Therefore, FDA estimates that approximately 150 manufacturers would be contacted in a 1-year period. It is also estimated from FDA experience that the survey will take approximately 20 to 30 minutes to complete over the telephone.

Dated: December 19, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 02–32850 Filed 12–27–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0282]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Participation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by January 29, 2003.

**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: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Notice of Participation (OMB Control Number 0910–0191)—Extension**

The regulations in § 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. Section 12.45 also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25), concerning disclosure of data and information by participants. In accordance with § 12.45(e), the presiding officer may omit a participant's appearance. The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation. The respondents are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit groups and institutions.

In the **Federal Register** of July 18, 2002 (67 FR 47387), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 12.45 | 340 | 1 | 340 | 3 | 1,020 |

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

The agency bases this estimate on past notices filed in which each notice of participation took an estimated 3 hours to complete.

Dated: December 20, 2002.

**Margaret M. Dotzel,**

*Assistant Commissioner for Policy.*

[FR Doc. 02–32849 Filed 12–27–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0509]**

### International Conference on Harmonisation; Draft Guidance on the M4 Common Technical Document—Quality: Questions and Answers/ Location Issues; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Common Technical Document—Quality: Questions and Answers/ Location Issues.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In the **Federal Register** of October 16, 2001 (66 FR 52634), FDA announced the availability of an ICH guidance entitled ''M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use'' (M4 CTD). This draft guidance provides further clarification for preparing the quality components of an application file in the CTD format (M4Q: The CTD-Quality). The draft guidance addresses: (1) The relationship between linked sections for certain parameters (such as polymorphism and particle size), and (2) location issues (by indicating the section in which to place requested information). The draft guidance is intended to ease the preparation of paper and electronic submissions, facilitate regulatory reviews, and simplify the exchange of regulatory information among regulatory authorities.

**DATES:** Submit written or electronic comments on the draft guidance by February 28, 2003.

**ADDRESSES:** Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug