Dated: July 10, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0333]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance: Emergency Use Authorization of Medical Products

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (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.

Draft Guidance: Emergency Use Authorization of Medical Products

The Federal Food, Drug, and Cosmetic Act (the act) permits the Commissioner of FDA (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the act (21 U.S.C. 360bbb–3). The data to support issuance of an emergency use authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the act, the Commissioner may establish conditions on the approval of an EUA. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the act also gives the Commissioner authority to establish other conditions on an authorization that the Commissioner finds to be necessary or appropriate to protect the public health.

For purposes of estimating the burden of reporting, FDA has established six categories of respondents which include: (1) Those who file a Request for Consideration for an EUA after a determination of actual or potential emergency and, in lieu of submitting the data, provide reference to a pending or approved application; (2) those who file a Request for Consideration for an EUA and the data after a determination of actual or potential emergency, without reference to a pending or approved application; (3) those who submit data to FDA on a candidate EUA product, which is subject to a pending or approved application, prior to a determination of actual or potential emergency; (4) those who submit data to FDA prior to a determination of actual or potential emergency about a candidate EUA product for which there is no pending or approved application; (5) manufacturers of an unapproved EUA product who must report to FDA regarding such activity; and (6) State and local public health officials who carry out an activity related to an unapproved EUA product (e.g., administering the product to civilians) and who must report to FDA regarding such activity.

For purposes of estimating the burden of recordkeeping, FDA has calculated the anticipated burden on manufacturers of unapproved products authorized for emergency use. The agency anticipates that the Federal Government will perform some of the additional recordkeeping necessary for unapproved products (e.g., related to the administration of unapproved EUA products to military personnel). FDA also anticipates that some State and local public health officials may be required to perform additional recordkeeping (e.g., related to the administration of unapproved EUA products to civilians) and calculated a recordkeeping burden for those activities.

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, because those products already are subject to approved collections of information (adverse experience reporting for biological products is approved under OMB control number 0910–0308 through May 31, 2005; adverse drug experience reporting is approved under OMB control number 0910–0230 through September 30, 2005; and investigational new drug applications (IND) regulations are approved under OMB control number 0910–0014 through January 31, 2006), and any additional burden imposed by this proposed collection would be minimal. Thus, FDA estimates the burden of this collection of information as follows:

The annual burden estimate for this information collection is 1,414 hours. The estimated reporting burden for this collection is 754 hours and the estimated recordkeeping burden is 660 hours.

In the **Federal Register** of July 5, 2005 (70 FR 38689), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received on the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Consideration; Pending application on file	1	1	1	15	15
Request for Consideration; No application pending	1	1	1	50	50
Pre-emergency submissions; Pending application on file	10	1	10	20	200
Pre-emergency submissions; No application pending	3	1	3	75	225
Manufacturers of an unapproved EUA product	3	4	12	2	24
State and local public health officials; Unapproved EUA product	30	4	120	2	240
Total					754

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Manufacturers of an unapproved EUA product	3	4	12	25	300
State and local public health officials; Unapproved EUA product	30	4	120	3	360
Total					660

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

Dated: July 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on a Public Advisory Committee; Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Pediatric Advisory Committee in the Office of the Commissioner. Nominations will be accepted for vacancies that have occurred on or before June 30, 2006.

FDA has special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: No cutoff date is established for the receipt of nominations. However, nominations received on or before July 28, 2006, will be given first consideration for membership on the Pediatric Advisory Committee.

ADDRESSES: All nominations for membership should be sent to Jan Johannessen (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Jan N. Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, FAX 301–827–3042, e-mail: *Jan.Johannessen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Pediatric Advisory Committee. There are currently six vacancies on this committee. These vacancies need to be filled as soon as possible.

I. Function of the Pediatric Advisory Committee

The committee advises the Commissioner of Food and Drugs on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary of Health and Human Services under 21 CFR 50.54 for products regulated by FDA and 45 CFR 46.407 on research involving children as