whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The agency suggests submitting the following information with a formal request for dispute resolution: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Respondents are expected to be sponsors, applicants, or manufacturers of drug or biological products regulated by the agency under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) who request formal resolution of a scientific or procedural dispute.

Provided below is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately eight sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 10 requests annually and CBER receives approximately 1 request annually. The hours per response are the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 88 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Requests for Formal Dispute Resolution	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	8	1.25	10	8	80
CBER	1	1	1	8	8
Total					88

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

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21156 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0516]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 2005 Food Safety Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''2005 Food Safety Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 24, 2005 (70 FR 29768), 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 0910–0345. The approval expires on February 30, 2008.

A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21157 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0216]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Humanitarian Use Devices

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 November 23, 2005.

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 comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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

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.

Medical Devices: Humanitarian Use Devices—21 CFR Part 814 (OMB Control Number 0910–0332)—Extension

This collection implements the humanitarian use device (HUD) Provision under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and 21 CFR part 814, subpart H. Under section 520(m) of the act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device do the following: (1) Is used to treat or diagnosis a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted, and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The information collection will allow FDA to determine whether to do the following: (1) Grant HUD designation of a medical device, (2) exempt a HUD from the effectiveness requirements in sections 514 and 515 of the act provided that the device meets requirements set forth in section 520(m) of the act, and (3) grants marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making those determinations. Also, this information enables FDA to determine whether the holder of a HUD is in compliance with the HUD requirements.

Description of Respondents: Businesses or others for-profit.

In the **Federal Register** of June 16, 2005 (70 FR 35098), 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 Respondent	Total Annual Responses	Hours per Response	Total Hours
814.102	20	1	20	40	800
814.104	8	1	8	320	2,560
814.106	8	2	16	50	800
814.108	20	1	20	80	1,600
814.116(e)(3)	1	1	1	1	1
814.124(a)	5	1	5	1	5
814.124(b)	1	1	1	2	2
814.126(b)(1)	35	1	35	120	4,200
Total					9,968

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
814.126(b)(2)	35	1	35	2	70

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

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21158 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

MicroArray Quality Control Project Meeting on MicroArray Quality Control; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''MicroArray Quality Control (MAQC) Project Meeting on MicroArray Quality Control.'' The focus of the 2-day meeting will be to review the datasets generated by the MAQC study.

Date and Time: The meeting will be held on Thursday, December 1, 2005, from 8 a.m. to 5 p.m. and Friday, December 2, 2005, from 8 a.m. to 2 p.m.

Location: The meeting will be held at the Crowne Plaza Cabana Portofino Room on December 1, 2005, and the St. Tropez Room on December 2, 2005, 4290 El Camino Real, Palo Alto, CA 94306, 650–857–0787, FAX: 650–496–1939, Web site: *http://www.cppaloalto.crowneplaza.com/*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact: Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7387, FAX: 870–543–7686, e-mail: *leming.shi@fda.hhs.gov*.

Registration: There will be no registration fee for attending the meeting. However, interested parties should send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person (see *Contact*) at least 15 days in advance of the meeting. Participants are responsible for their own costs of travel, lodging, and meals.

FDA welcomes the attendance of the public at this meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jeannette Coleman at 870–543–7087, e-mail: *jeanette.coleman@fda.hhs.gov*, at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION: FDA's critical path initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA issued the ''Guidance for Industry: Pharmacogenomic Data Submissions'' (*http://www.fda.gov/cder/guidance/6400fnl.pdf*) to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development and medical diagnostics. A microarray is a tool for analyzing gene expression that consists of a small membrane or glass slide containing samples of many genes arranged in a regular pattern. Microarrays represent a core technology in pharmacogenomics; however, before this technology can successfully and reliably be applied in clinical practice and regulatory decisionmaking, standards and quality measures need to be developed.

The MAQC project involves six FDA centers, major providers of microarray platforms and ribonucleic acid (RNA) samples, government agencies, academic laboratories, and other stakeholders. The MAQC project aims to evaluate quality control metrics and thresholds for objectively assessing the performance achievable by various microarray platforms, and evaluating the advantages and disadvantages of various data analysis methods. Two RNA samples will be selected for three species (i.e., human, rat, and mouse), and differential gene expression levels between the two samples will be calibrated with microarrays and other technologies (e.g., quantitative real time-polymerase chain reaction (qRT–PCR)). The resulting microarray datasets will be used for assessing the precision and crossplatform/laboratory comparability of microarrays, and the qRT–PCR datasets will enable evaluation of the nature and magnitude of any systematic biases that may exist between microarrays and qRT–PCR. The availability of the calibrated RNA samples and the resulting microarray and qRT–PCR datasets, which will be made readily accessible to the microarray community, will allow individual laboratories to identify and correct procedural failures more easily. The MAQC project will help improve the microarray technology and foster its proper applications in discovery, development and review of FDA-regulated products. For more information about the MAQC project, please visit *http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/*.

At the public meeting, each participating platform provider will give a 15-minute presentation to summarize the datasets generated by its test sites and to describe its analysis results. Each analysis site will also give a 15-minute presentation on its analysis results. Other interested parties may present data, information, or views, orally or in writing, on issues related to microarray quality control and data analysis. Those desiring to make formal oral presentations should notify the contact person (see *Contact*) before November 4, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present with an indication of the approximate time requested to make the presentation.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21152 Filed 10–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Injuries Among Youth With Developmental Disabilities

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Injuries Among Youth with Developmental Disabilities. *Type of Information Collection Request:* New. *Use of Information:* The proposed study seeks (1) to determine if children with disabilities are at increased risk of injury compared to typically developing children, and (2) to identify which injuries children with developmental disabilities are at particular risk of sustaining. Existing data on this topic are scarce and equivocal. Results will help inform prevention efforts. NICHD proposes to collect information about disabilities among children with injuries through phone interviews with