and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed which may result in public harm.

Section 1860D–23 and 1860D–24 of the Social Security Act, added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), requires the Secretary to establish requirements for prescription drug plans to ensure the effective coordination between Part D plans, State pharmaceutical assistance programs and other payers. These requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464.

Part D sponsors will be responsible for making system changes related to enrollment file sharing, claims processing and payment, reconciliation and tracking of the true out-of-pocket expenditures of beneficiaries prior to the implementation of Part D (January 1, 2006). System changes must also be implemented by State pharmaceutical assistance programs so that they may provide additional drug benefits at the pharmacy to Part D beneficiaries. In addition to making system changes, these changes must be tested, which will require additional time prior to January 1, 2006. Failure to make system changes may result in the delay in the implementation of the program and may result in a direct harm to beneficiaries since delays or mistakes in claims processing may result in beneficiaries not receiving their medications, or being unable to pay for medications out-of-pocket until the system issue is resolved.

CMS is requesting OMB review and approval of this collection by November 8, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by November 7, 2005.

Type of Information Collection Request: New Collection; *Title of Information Collection:* Coordination of Benefits between Part D Plans and Other Prescription Coverage Providers; *Use:* This information is necessary to assist with coordination of prescription drug benefits provided to the Medicare beneficiary at the pharmacy; *Form Number:* CMS–10171 (OMB#: 0938–NEW); *Frequency:* On occasion and monthly; *Affected Public:* Business or other for-profit, Federal, State, Local and Tribal Government; *Number of Respondents:* 56,320; *Total Annual Responses:* 2,153,767,270; *Total Annual Hours:* 1,017,914.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *paperwork@cms.hhs.gov,* or call the Reports Clearance Office at (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received by the designees referenced below by November 7, 2005: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Melissa Musotto, CMS–10171. and, OMB Human Resources and Housing Branch, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: September 30, 2005.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–20229 Filed 10–6–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0178]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Regulations Under the Federal Import Milk Act

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 7, 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.

Under the regulations implementing the Federal Import Milk Act (FIMA) (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the

milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50° F. In addition, the regulations in part 1210 (21 CFR part 1210) require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

In the **Federal Register** of May 31, 2005 (70 FR 30951), FDA published a 60-day notice requesting public comment on the information collection provisions.

FDA received one letter in response, which contained several comments and suggestions. These suggestions and FDA's responses follow.

The comment stated that the collection of information in forms FDA 1815, FDA 1993, FDA 1994, FDA 1995, FDA 1996, and FDA 1997 is necessary and that most of these forms provide practical information. However, the comment requested a number of changes to the forms. First, the comment suggested that certification of tuberculosis-free status in Form FDA 1815 and Form FDA 1994 should be done in a manner consistent with the U.S. Department of Agriculture's Animal Plant Health and Inspection Service (APHIS) guidelines entitled ''Bovine Tuberculosis Eradication Uniform Methods and Rules'' (APHIS 91–45–011). Another comment suggested that that Form FDA 1815 and Form FDA 1995 include a requirement that the submitter certify that the dairy cows are free from brucellosis and that the certification of brucellosis-free status should be done in a manner consistent with the APHIS guidelines published in the document entitled ''Brucellosis Eradication: Uniform Methods and Rules'' (APHIS 91–45–013).

FDA agrees that, where possible, Federal agencies should act in a consistent manner. However, FDA declines to make the suggested changes to its forms because such changes are not necessary. The two referenced documents are published by APHIS as part of its national animal disease eradication efforts undertaken by the National Center for Animal Health Programs under the statutory authority provided by the Animal Health Protection Act (7 U.S.C. 8301–8320). These are domestic programs in the United States which are designed to address the general health status of U.S. domestic cattle. Under the statutory authority provided by FIMA, FDA regulates all foreign-produced milk and cream imported into the United States. FIMA requires certification of the general health of the animal, which certification is obtained by FDA on Form FDA 1995. Although the two statutory authorities may differ, the practices presented in the APHIS documents already are being followed by FDA. FDA considers the status of the brucellosis and tuberculosis control programs in the country offering milk for importation into the United States and bases its acceptance decision on that status.

Another comment stated that Form FDA 1996 and Form FDA 1997 do not provide practical information and should be made consistent with Form FDA 2359a, which, the comment states, is ''utilized to ensure milk sanitation standards are met at the farm level.''

FDA disagrees that Form FDA 1996, ''Dairy Farm Sanitation Report,'' and Form FDA 1997, ''Score Card for Sanitary Inspection of Milk Plants,'' do not provide practical information. The information collected on these two forms is used by the agency in determining whether the imported milk or cream offered for import meet FIMA's requirements for sanitary inspections of dairy farms and plants (21 U.S.C. 142). FDA also disagrees that the two forms should be made consistent with Form FDA 2359a because that form is used domestically for inspection of facilities producing Grade ''A'' milk products. FDA does not use it for inspections of facilities producing manufacturing-grade milk domestically. Thus, it would be inappropriate for FDA to use it for inspection of foreign facilities manufacturing non-Grade ''A'' milk products.

The comment also opposed electronic submission of the forms and suggested that several changes should be made to the requirements of FIMA and the agency's related Compliance Policy Guide. These comments are outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

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

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	8	1	8	0.5	4.0
FDA 1993/Application of permit	1210.20	8	1	8	0.5	4.0
FDA 1994/Tuberculin test	1210.13	1	1	1	0.5	0.5
FDA 1995/Physical examination of cows	1210.12	1	1	1	0.5	0.5
FDA 1996/Sanitary inspection of dairy farms	1210.11	8	200	1,600	1.5	2,400

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1997/Sanitary inspections of plants	1210.14	8	1	8	2.0	16.0
Totals						2,425.0

[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 Record	Total Annual Records	Hours per Recordkeeper	Total Hours
1210.15	8	1	8	.05	0.40

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

These estimates are based on the number of current permit holders and the number of inquiries that FDA has received regarding requests for applications in the past 3 years. No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. Low burden has been estimated for Forms FDA 1994 and 1995 because they are not are not used often. The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20148 Filed 10–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0404]

Pediatric Ethics Subcommittee of the Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of the Pediatric Ethics Subcommittee of the Pediatric Advisory Committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Ethics Subcommittee of the Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Pediatric Advisory Committee on FDA, and certain Department of Health and Human Services (HHS), regulatory issues.

Date and Time: The meeting will be held on November 15, 2005, from 8:30 a.m. to 4 p.m.

Addresses: Electronic copies of the documents for public review can be viewed at the Pediatric Advisory Committee (PAC) Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee meeting for 11–15–05.) Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select Docket No. 2005N–0404 entitled ''Leuprolide IRB Referral'' and follow the prompts to submit your statement. Written comments should be submitted to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please submit comments by 4:30 p.m. on November 1, 2005. Received comments may be viewed on the FDA Web site at: *http://www.fda.gov/ohrms/dockets*, or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Location: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C–06), Rockville, MD 20857, 301–827–6687, or by e-mail: *jjohannessen@fda.gov*. Please call the FDA Advisory Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001, for up-to-date information on this meeting.

Agenda: The Pediatric Ethics Subcommittee of the Pediatric Advisory Committee will meet to discuss a referral by an Institutional Review Board (IRB) of a proposed clinical investigation involving children as subjects, that is regulated by FDA and may be supported by HHS. The proposed clinical investigation is entitled ''Gonadotropin Releasing Hormone (GnRH) Agonist Test in Disorders of Puberty.'' Because the proposed clinical investigation would be regulated by FDA, and conducted or supported by HHS, both FDA and the Office for Human Research Protections, HHS, will participate in the meeting.

After presentation of an overview of the IRB referral process, background information on disorders of puberty and