Dated: June 3, 2005.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–20369 Filed 10–11–05; 8:45 am]

BILLING CODE 4160–70–M

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 Federal Committee meeting.

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates:

8:30 a.m.–5:15 p.m., October 26, 2005.
8 a.m.–3:30 p.m., October 27, 2005.

Place: Atlanta Marriott Century Center, 2000 Century Boulevard, N.E., Atlanta, Georgia 30345–3377.

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 United States Code 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; recommendations for use of Hepatitis A vaccine among children; VFC vote on Hepatitis A; adult Hepatitis B vaccine recommendation; varicella zoster immune globulin; recommended childhood and adolescent immunization schedules; use of Tdap vaccine; prevention of rotavirus gastroenteritis; Measles, Mumps, Rubella Vaccine (MMRV) recommendation; VFC vote on MMRV; Human Papailloma Virus vaccine; general recommendations on immunization; herpes zoster; and Departmental updates.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Demetria Gardner, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE., (E–61), Atlanta, Georgia 30333, telephone 404/639–8096, fax 404/639–8616.

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 ATSDR.

Dated: October 5, 2005.

Alvin Hall,

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

[FR Doc. 05–20381 Filed 10–11–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0393]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Regulations

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 extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

DATES: Submit written or electronic comments on the collection of information by December 12, 2005.

ADDRESSES: Submit electronic comments on the collection of information to:*http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 extension 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 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.

Investigational New Drug Regulations—21 CFR Part 312 (OMB Control Number 0910–0014)—Extension

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in the FDA regulation ''Investigational New Drug Application'' in part 312 (21 CFR part 312). This regulation implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves

an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of investigational new drugs.

The IND information collection requirements provide the means by which FDA can do the following: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug's effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; (8) obtain other information pertinent to determining whether clinical testing should be continued and information related to the protection of human subjects. Without the information provided by industry in response to the IND regulations, FDA cannot authorize or monitor the clinical investigations which must be conducted prior to authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study's progress, to assure subject safety, to assure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

There are two forms that are required under part 312. The first is Form FDA–1571 ''Investigational New Drug Application.'' A person who intends to conduct a clinical investigation submits this form to FDA. It includes the following information: (1) A cover sheet containing background information on the sponsor and investigator, (2) a table of contents, (3) an introductory statement and general investigational plan, (4) an investigator's brochure describing the drug substance, (5) a protocol for each planned study, (6) chemistry, manufacturing, and control information for each investigation, (7) pharmacology and toxicology information for each investigation, and (8) previous human experience with the investigational drug.

The second form required under part 312 is Form FDA–1572 ''Investigator Statement.'' Before permitting an investigator to begin participation in an investigation, the sponsor must obtain and record this form. It includes background information on the investigator and the investigation, and a general outline of the planned investigation and the study protocol.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements in part 312:

TABLE 1.

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
312.7(d)	Applications for permission to sell an investigational new drug.
312.10(a)	Applications for waiver of requirements under part 312. Estimates for this requirement are included under §§ 312.23 and 312.31.
312.20(c)	Applications for investigations involving an exception from informed consent under § 50.24 (21 CFR 50.24). Estimates for this requirement are included under § 312.23.
312.23	INDs (content and format).
(a)(1)	Cover sheet FDA–1571.
(a)(2)	Table of contents.
(a)(3)	Investigational plan for each planned study.
(a)(5)	Investigator's brochure.
(a)(6)	Protocols—phases 1, 2, and 3.
(a)(7)	Chemistry, manufacturing, and control information.
(a)(7)(iv)(*a*), (a)(7)(iv)(*b*), and (a)(7)(iv)(*c*)	A description of the drug substance, a list of all components, and any placebo used.
(a)(7)(iv)(*d*)	Labeling: Copies of labels and labeling to be provided each investigator.
(a)(7)(iv)(*e*)	Environmental impact analysis regarding drug manufacturing and use.
(a)(8)	Pharmacological and toxicology information.
(a)(9)	Previous human experience with the investigational drug.
(a)(10)	Additional information.
(a)(11)	Relevant information.
(f)	Identification of exception from informed consent.
312.30	Protocol amendments.
(a)	New protocol.
(b)	Change in protocol.
(c)	New investigator.
(d)	Content and format.
(e)	Frequency.
312.31	Information amendments.

TABLE 1.—Continued

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
(b)	Content and format. Chemistry, toxicology, or technical information.
312.32	Safety reports.
(c)(1)	Written reports to FDA and to investigators.
(c)(2)	Telephone reports to FDA for fatal or life-threatening experience.
(c)(3)	Format or frequency.
(d)	Followup submissions.
312.33	Annual reports.
(a)	Individual study information.
(b)	Summary information.
(b)(1)	Adverse experiences.
(b)(2)	Safety report summary.
(b)(3)	List of fatalities and causes of death.
(b)(4)	List of discontinuing subjects.
(b)(5)	Drug action.
(b)(6)	Preclinical studies and findings.
(b)(7)	Significant changes.
(c)	Next year general investigational plan.
(d)	Brochure revision.
(e)	Phase I protocol modifications.
(f)	Foreign marketing developments.
312.35	Treatment use of investigational new drugs.
(a)	Treatment protocol submitted by an investigational new drug sponsor.
(b)	Treatment investigational new drug application (IND) submitted by licensed practitioner.
312.36	Requests for emergency use of an investigational new drug.
312.38(b) and (c)	Notification of withdrawal of an investigational new drug.
312.42(e)	Sponsor requests that a clinical hold be removed and submits a complete response to the issues identified in the clinical hold order.
312.44(c) and (d)	Opportunity for sponsor response to FDA when an investigational new drug is terminated.
312.45(a) and (b)	Sponsor request for, or response to, inactive status determination of an investigational new drug.
312.47(b)	''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings.
312.53(c)	Investigator information. Investigator report (Form FDA–1572) and narrative; Investigator's background information; phase 1 outline of planned investigation; and phase 2 outline of study protocol; financial disclosure information.
312.54(a) and (b)	Sponsor submissions concerning investigations involving an exception from informed consent under § 50.24.
312.55(b)	Sponsor reports to investigators on new observations, especially adverse reactions and safe use. Only ''new observations'' are estimated under this section; investigator brochures are included under § 312.23.
312.56(b), (c), and (d)	Sponsor monitoring of all clinical investigations, investigators, and drug safety; notification to FDA.
312.58(a)	Sponsor's submission of records to FDA on request.
312.64	Investigator reports to the sponsor.
(a)	Progress reports.
(b)	Safety reports
(c)	Final reports.
(d)	Financial disclosure reports.
312.66	Investigator reports to Institutional Review Board. Estimates for this requirement are included under § 312.53.
312.70(a)	Investigator disqualification; opportunity to respond to FDA.
312.83	Sponsor submission of treatment protocol. Estimates for this requirement are included under §§ 312.34 and 312.35.
312.85	Sponsors conducting phase 4 studies. Estimates for this requirement are included under § 312.23 in OMB control number 0910–0014, and §§ 314.50, 314.70, and 314.81 (21 CFR 314.50, 314.70, and 314.81) in OMB control number 0910–0001.
312.110(b)	Request to export an investigational drug.
312.120(b) and (c)(2)	Sponsor's submission to FDA for use of foreign clinical study to support an IND. Estimates for this requirement are included under §§ 312.23 and 312.30 in OMB control number 0910–0014, and §§ 314.50, 314.60, and 314.70 (21 CFR 314.60) in OMB control number 0910–0001.
312.120(c)(3)	Sponsor's report to FDA on findings of independent review committee on foreign clinical study. Estimates for this requirement are included under §§ 312.23 and 312.30 in OMB control number 0910–0014, and §§ 314.50, 314.60, and 314.70 in OMB control number 0910–0001.

TABLE 1.—Continued

REPORTING REQUIREMENTS	
21 CFR Section	Requirements
312.130(d)	Request for disclosable information for investigations involving an exception from informed consent under § 50.24.
RECORDKEEPING REQUIREMENTS	
21 CFR Section	Requirements
312.52(a)	Transfer of obligations to a contract research organization.
312.57(a) and (b)	Sponsor recordkeeping.
312.59	Sponsor recordkeeping of disposition of unused supply of drugs. Estimates for this requirement are included under § 312.57.
312.62(a)	Investigator recordkeeping of disposition of drugs.
312.62(b)	Investigator recordkeeping of case histories of individuals.
312.160(a)(3)	Records maintenance: shipment of drugs for investigational use in laboratory research animals or in vitro tests.
312.160(c)	Shipper records of alternative disposition of unused drugs.

In tables 2 and 3 of this document, the estimates for ''No. of Respondents,'' ''No. of Responses per Respondent,'' and ''Total Annual Responses'' were obtained from the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) reports and data management systems for submissions received in 2004 and from other sources familiar with the number of submissions received under part 312. The estimates for ''Hours per Response'' were made by CDER and CBER individuals familiar with the burden associated with these reports and from estimates received from the pharmaceutical industry.

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

TABLE 2.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR HUMAN DRUGS[1]

REPORTING BURDEN					
21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.7(d)	9	1.4	13	24	7,488
312.23(a) through (f)	1,245	1.3	1,597	1,600	2,555,200
312.30(a) through (e)	1,257	13.3	16,687	284	4,739,108
312.31(b)	1,116	7.4	8,298	100	829,800
312.32(c) and (d)	649	24.7	16,052	32	513,664
312.33(a) through (f)	1,821	2.5	4,516	360	1,625,760
312.35(a) and (b)	5	1.2	6	300	1,800
312.36	109	1.1	121	16	1,936
312.38(b) and (c)	536	1.3	677	28	18,965
312.42(e)	97	1.2	118	284	33,512
312.44(c) and (d)	44	1	45	16	720
312.45(a) and (b)	185	1.5	271	12	3,252
312.47(b)	215	1.7	355	160	56,800
312.53(c)	21,194	1	21,194	80	1,695,520
312.54(a) and (b)	0	0	0	48	0
312.55(b)	807,400	1	807,400	48	38,755,200
312.56(b), (c), and (d)	13	1	13	80	1,040

TABLE 2.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR HUMAN DRUGS[1]—Continued

REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.58(a)	88	3.8	340	8	2,720
312.64(a) through (d)	31,791	1	31,791	24	762,984
312.70(a)	4	1	4	40	160
312.110(b)	33	8.3	276	75	20,700
312.130(d)	5	1	5	8	40
Total reporting burden					51,626,369

RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
312.52(a)	335	1.5	488	2	976
312.57(a) and (b)	335	119.8	40,148	100	4,014,800
312.62(a)	20,074	1	20,074	40	802,960
312.62(b)	200,740	1	200,740	40	8,029,600
312.160(a)(3)	372	1.5	542	.5	271
312.160(c)	372	1.5	542	.5	271
Total recordkeeping burden					12,848,878
Human drugs total burden hours					64,475,247

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

TABLE 3.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR BIOLOGICS[1]

REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.7(d)	41	1.4	58	24	1,392
312.23(a) through (f) and 312.120(b), (c)(2), and (c)(3)	433	1.3	557	1,808	1,007,056
312.30(a) through (e)	590	6.8	4,014	284	1,139,976
312.31(b)	263	29.3	7,700	100	770,000
312.32(c) and (d) and 312.56(c)	294	13.7	4,042	32	129,344
312.33(a) through (f) and 312.56(c)	647	2.3	1,473	360	530,280
312.35(a) and (b)	1	1	1	300	300
312.36	6	1	6	16	96
312.38(b) and (c)	117	1.3	153	28	4,284
312.42(e)	74	1.5	108	284	30,672
312.44(c) and (d)	17	1.1	18	16	288
312.45(a) and (b)	60	1.8	107	12	1,284
312.47(b)	43	1.5	66	160	10,560
312.53(c)	348	6.6	2,303	80	184,240

TABLE 3.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR BIOLOGICS[1]—Continued

REPORTING BURDEN

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.54(a) and (b)	1	1	1	48	48
312.55(b)	138	2.5	347	48	16,656
312.56(b) and (d)	14	1.6	23	80	1,840
312.58(a)	8	1	8	8	64
312.64(a) through (d)	6,003	3.5	21,185	24	508,440
312.70(a)	6	1	6	40	240
312.110(b)	21	1	21	75	1,575
312.130(d)	1	1	1	8	8
Total reporting burden					4,338,643

RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
312.52(a)	139	1.4	200	2	400
312.57(a) and (b)	433	2.6	1,114	100	111,400
312.62(a)	5,570	1	5,570	40	222,800
312.62(b)	5,570	10	55,700	40	2,228,000
312.160(a)(3)	146	1.4	211	0.5	105.5
312.160(c)	146	1.4	211	0.5	105.5
Total recordkeeping burden					2,562,811
Total biologics burden hours					6,901,454

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

TABLE 4.—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN FOR HUMAN DRUGS AND BIOLOGICS[1]

Total human drugs burden hours	64,475,247
Total biologics burden hours	6,901,454
Total burden hours	71,376,701

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

Dated: October 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20362 Filed 10–11–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel. ''Review of an Unsolicited P01.''

Date: October 26, 2005.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Cheryl K. Lapham, PhD, Scientific Review Administrator, Scientific Review Program, National Institute of Allergy and Infectious Diseases, DEA/NIH/DHHS, 6700–B Rockledge Drive, MSC 7616, Room 3127, Bethesda, MD 20892–7616, 301–402–4598, *clapham@niaid.nih.gov.*