businesses or other for-profit institutions or groups.

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
10.30	120	1	120	12	1,440

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

Dated: August 6, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–20794 Filed 8–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0926]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Regulations Under the Federal Import Milk Act; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 26, 1999 (64 FR 40379). The document announced an opportunity for public comment on a collection of information that had been submitted to the Office of Management and Budget for review and clearance.

DATES: August 12, 1999.

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

SUPPLEMENTARY INFORMATION: In FR Doc. 99–18927, appearing on page 40379 in the **Federal Register** of Monday, July 26, 1999, the following correction is made:

1. On page 40379, in the third column, in the first full paragraph, beginning in the fourth line, ''No comments were received.'' is corrected to read ''One comment was received that was supportive of the Federal Import Milk Act and encouraged FDA to continue this information collection request.''

Dated: August 5, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–20793 Filed 8–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1010]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Investigational New Drug Regulations

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 (the PRA).

DATES: Submit written comments on the collection of information by September 13, 1999.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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

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

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in FDA's regulation ''Investigational New Drug Application'' 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: (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: Form FDA–1571—''Investigational New Drug Application.''A person who intends to conduct a clinical investigation submits this form to FDA. It includes: (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.

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	Explanations
312.7(d)	Applications for permission to sell an investigational new drugs.
312.10(a)	Applications for waiver of requirements under part 312. Only emergency requests are estimated under this section; other requests 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	IND's (content and format).
312.23(a)(1)	Cover sheet FDA–1571.
312.23(a)(2)	Table of contents.
312.23(a)(3)	Investigational plan for each planned study.
312.23(a)(5)	Investigator's brochure.
312.23(a)(6)	Protocols—Phase 1, 2, and 3.
312.23(a)(7)	Chemistry, manufacturing, and control information.
312.23(a)(7)(iv)(*a*), (*b*), and (*c*)	A description of the drug substance, a list of all components, and any placebo used.
312.23(a)(7)(iv)(*d*)	Labeling—copies of labels and labeling to be provided each investigator.
312.23(a)(7)(iv)(*e*)	Environmental impact analysis regarding drug manufacturing and use.
312.23(a)(8)	Pharmacological and toxicology information.
312.23(a)(9)	Previous human experience with the investigational drug.
312.23(a)(10)	Additional information.
312.23(a)(11)	Relevant information.
312.23(f)	Identification of exception from informed consent.
312.30	Protocol amendments.
312.30(a)	New protocol.
312.30(b)	Change in protocol.
312.30(c)	New investigator.
312.30(d)	Content and format.
312.30(e)	Frequency.
312.31	Information amendments.
312.31(b)	Content and format.
	Chemistry, toxicology, or technical information.
312.32	Safety reports.
312.32(c)(1)	Written reports to FDA and to investigators.
312.32(c)(2)	Telephone reports to FDA for fatal or life-threatening experience.
312.32(c)(3)	Format or frequency.
312.32(d)	Followup submissions.
312.33	Annual reports.
312.33(a)	Individual study information.
312.33(b)	Summary information.
312.33(b)(1)	Adverse experiences.
312.33(b)(2)	Safety report summary.
312.33(b)(3)	List of fatalities and causes of death.
312.33(b)(4)	List of discontinuing subjects.

TABLE 1.—REPORTING REQUIREMENTS—Continued

21 CFR Section	Explanations
312.33(b)(5)	Drug action.
312.33(b)(6)	Preclinical studies and findings.
312.33(b)(7)	Significant changes.
312.33(c)	Next year general investigational plan.
312.33(d)	Brochure revision.
312.33(e)	Phase I protocol modifications.
312.33(f)	Foreign marketing developments.
312.35	Treatment use of investigational new drugs.
312.35(a)	Treatment protocol submitted by IND sponsor.
312.35(b)	Treatment IND submitted by licensed practitioner.
312.36	Requests for emergency use of an investigational new drugs.
312.38(b) and (c)	Notification of withdrawal of an IND.
312.44(c) and (d)	Opportunity for sponsor response to FDA when IND is terminated.
312.45(a) and (b)	Sponsor request for or response to inactive status determination of an IND.
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.
312.64(a)	Progress reports.
312.64(b)	Safety reports.
312.64(c)	Final reports.
312.64(d)	Financial disclosure reports.
312.66	Investigator reports to Institutional Review Board. Estimates for this requirement are included under § 312.53.
312.70	Investigator disqualification; opportunity to respond to FDA. Estimates for this requirement are not included in the estimates for part 312.
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 these postmarketing studies are not included in the estimates for part 312.
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.
312.120(c)(3)	Sponsor's report to FDA on findings of independent review committee on foreign clinical study.
312.130(d)	Request for disclosable information for investigations involving an exception from informed consent under § 50.24.

TABLE 2.—RECORDKEEPING REQUIREMENTS

21 CFR Section	Explanations
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)	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 the **Federal Register** of May 6, 1999 (64 FR 24402), the agency requested comments on the proposed collections of information. No comments were received.

TABLE 3.—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS[1]

21 CFR Section	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
312.7(d)	7	1	7	24	168
312.10(a)	0	0	0	0	0
312.23(a) and (f)	1,601	1.25	1,996	1,600	3,193,600
312.30(a) through (e)	918	14.85	13,629	284	3,870,636
312.31(b)	760	8.87	6,738	100	673,800
312.32(c) and (d)	459	14.33	6,576	32	210,432
312.33(a) through (f)	1,841	2.35	4,318	350	1,511,300
312.35(a) and (b)	1	1	1	300	300
312.36	643	1.2	720	16	11,520
312.38(b)	621	1.24	773	28	21,644
312.38(c)	621	1.24	773	160	123,680
312.44(c) and (d)	710	1.10	780	16	12,480
312.45(a) and (b)	294	1.32	389	12	4,668
312.47(b)	252	1	252	160	40,320
312.53(c)	4,500	1	4,500	80	360,000
312.54(a) and (b)	4	1	4	48	192
312.55(b)	4,500	1	4,500	48	216,000
312.56(b), (c), and (d)	5	1	5	80	400
312.58(a)	337	1	337	8	2,696
312.64(a) through (d)	8,200	1	8,200	24	196,800
312.110(b)	150	2	303	75	22,725
312.120(b) and (c)(2)	100	2	200	168	33,600
312(c)(3)	100	2	200	40	8,000
312.130(d)	4	1	4	8	32
Total Reporting Burden					10,514,993

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

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

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.52(a)	360	1	360	2	720
312.57(a) and (b)	4,000	2.05	8,200	100	400,000
312.62(a)	8,200	1	8,200	40	328,000
312.62(b)	8,200	12.2	100,000	40	328,000
312.160(a)	3,400	7.35	25,000	30 min	1,700
312.160(c)	3,400	2.35	8,000	30 min	1,700
Total Recordkeeping Burden					1,060,120
Human Drugs Total Burden Hours					11,575,113

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

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS[1]

21 CFR Section	No. of Respondents	No. of Responses Per Response	Total Annual Responses	Hours per Response	Total Hours
312.7(d)	9	1.3	12	24	288
312.10(a)	1	1	1	40	40
312.23(a) and (f) and 312.120(b), (c)(2), and (c)(3)	278	1.8	492	1,600	787,200
312.30(a) and (e)	975	6.5	6,411	284	1,820,724
312.31(b)	975	9.2	9,005	100	900,500
312.32(c) and (d) and 312.56(c)	602	6.7	4,034	32	129,088
312.33(a) and (f) and 312.56(c)	1,253	1.6	1,989	350	696,150
312.35(a) and (b)	1	1	1	300	300
312.36	22	5.5	122	16	1,952
312.38(b)	128	1.7	212	28	5,936
312.38(c)	128	1.7	212	160	33,920
312.44(c) and (d)	55	1.9	107	16	1,712
312.45(a) and (b)	74	1.4	105	12	1,260
312.47(b)	150	1.8	274	160	43,840
312.53(c)	672	6.6	4,421	80	353,680
312.54(a) and (b)	4	1	4	48	192
312.55(b)	374	6.1	2,288	48	109,824
312.56(b) and (d)	12	1.6	20	80	1,600
312.58(a)	10	1	10	8	80
312.64(a) and (d)	5,014	1	5,014	24	120,336

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS[1]—Continued

21 CFR Section	No. of Respondents	No. of Responses Per Response	Total Annual Responses	Hours per Response	Total Hours
312.110(b)	10	1.3	13	75	975
312.130(d)	1	1	1	0.5	0.5
Total Reporting Burden					5,009,597.5

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

TABLE 6.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.52(a)	27	2.5	67	5	135
312.57(a) and (b)	1,253	2	2,506	100	125,300
312.62(a)	5,014	1	5,014	40	200,560
312.62(b)	8,200	12.2	100,000	40	328,000
312.160(a)	3,400	7.35	25,000	30 min	1,700
312.160(c)	320	1	320	0.5	160
Total Biologics Recordkeeping Hours					655,855
Total Biologics Burden Hours					5,665,452.5
Total Human Drugs Burden Hours					11,575,113
Total Combined Burdens					17,240,565.5

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

Dated: August 6, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–20846 Filed 8–11–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Criteria for Safety and Efficacy Evaluation of Oxygen Therapeutics as Red Cell Substitutes.'' This public workshop is intended to examine the current status of the safety of red cell substitutes at both the basic and preclinical science levels and review the clinical experiences gained by manufacturers in the course of the development of these products. The public workshop also is intended to address problems of efficacy evaluation and risk/benefit assessments in trauma and surgery.

Date and Time: The public workshop will be held on September 27, 1999, 8 a.m. to 5 p.m., and on September 28, 1999, 8 a.m. to 12:30 p.m.

Location: The public workshop will be held at the National Institutes of Health, Natcher Conference Center, Bldg. 45, Balconies A, B, and C, 45 Center Dr., Bethesda, MD.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration and Requests for Oral Presentations: Early registration by Friday, September 10, 1999, is recommended. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (address above). On-site registration, which will begin at 7 a.m., will be done on a space available basis on the day of the workshop. There is no registration fee for the workshop. Space is limited, therefore, interested parties are encouraged to register early. If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance. Requests for oral presentations should be sent by September 13, 1999, to Abdulilah Alayash, Center for Biologics Evaluation and Research, Division of Hematology, Bldg. 29, rm. 112, 8800 Rockville Pike, Bethesda, MD 20892, 301–827–3813, FAX 301–435–4034, or e-mail ''Alayash@cber.fda.gov''.

Agenda: The public workshop is intended to discuss a variety of issues concerning the safety and efficacy of red blood cell substitutes. The goals of the public workshop are to: (1) Review current understanding of toxicity issues, (2) define clinical endpoints for clinical trials in hemorrhagic shock and elective surgery, (3) consider whether physiological endpoint(s) could be used as surrogates in lieu of mortality and/or morbidity, and (4) discuss the therapeutic ''risk vs. benefit'' in using hemoglobin and fluorochemical-based products in trauma and surgery.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A– , Rockville, MD 20857, approximately 15 working days after the public workshop at cost of 10 cents per page. The public workshop transcript will also be available on the Center for Biologics Evaluation and Research website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: August 6, 1999

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–20845 Filed 8–11–99; 8:45 am]

BILLING CODE 4160–01–F