FDA based these estimates on the number of inquiries that have been received concerning the program and the number of requests for application forms over the past 3 years.

Dated: January 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1760 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0042]

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 either electronic or written comments on the collection of information by March 28, 2011.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov.* 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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850. 301–796–3792. *Elizabeth.Berbakos@fda.hhs.gov.*

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 (IND) 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 regulations "Investigational New Drug Application" in part 312 (21 CFR part 312). Part 312 implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) (the FD&C Act) 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:

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.

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:

Reporting Requirements

21 CFR 312.2(e)—Requests for FDA advice on the applicability of part 312 to a planned clinical investigation.
21 CFR 312.8—Charging for investigational drugs under an IND.
21 CFR 312.10—Applications for waiver of requirements under part 312. As indicated in § 312.10(a), estimates for this requirement are included under §§ 312.23 and 312.31. In addition, separate requests under § 312.10 are estimated in table 1 of this document.
21 CFR 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.
21 CFR 312.23—INDs (content and format).
21 CFR 312.23(a)(1)—Cover sheet FDA–1571.
21 CFR 312.23(a)(2) —Table of Contents.
21 CFR 312.23(a)(3)—Investigational plan for each planned study.
21 CFR 312.23(a)(5)—Investigator's brochure.
21 CFR 312.23(a)(6)—Protocols—Phase 1, 2, and 3.
21 CFR 312.23(a)(7)—Chemistry, manufacturing, and control information.
21 CFR 312.23(a)(7)(iv)(*a*),(*b*),(*c*)—A description of the drug substance, a list of all components, and any placebo used.
21 CFR 312.23(a)(7)(iv)(*d*)—Labeling: Copies of labels and labeling to be provided each investigator.
21 CFR 312.23(a)(7)(iv)(*e*)—Environmental impact analysis regarding drug manufacturing and use.
21 CFR 312.23(a)(8)—Pharmacological and toxicology information.
21 CFR 312.23(a)(9)—Previous human experience with the investigational drug.
21 CFR 312.23(a)(10)—Additional information.
21 CFR 312.23(a)(11)—Relevant information.
21 CFR 312.23(f)—Identification of exception from informed consent.
21 CFR 312.30—Protocol amendments.
21 CFR 312.30(a)—New protocol.
21 CFR 312.30(b)—Change in protocol.
21 CFR 312.30(c)—New investigator.
21 CFR 312.30(d)—Content and format.
21CFR 312.30(e)—Frequency.
21 CFR 312.31—Information amendments.
21CFR 312.31(b)—Content and format.
—Chemistry, toxicology, or technical information.
21 CFR 312.32—Safety reports.
21 CFR 312.32(c)(1)—Written reports to FDA and to investigators.
21 CFR 312.32(c)(2)—Telephone reports to FDA for fatal or life-threatening experience.
21 CFR 312.32(c)(3)—Format or frequency.
21 CFR 312.32(d)—Follow up submissions.
21 CFR 312.33—Annual reports.
21 CFR 312.33(a)—Individual study information.
21 CFR 312.33(b)—Summary information.
21 CFR 312.33(b)(1)—Adverse experiences.
21 CFR 312.33(b)(2)—Safety report summary.
21 CFR 312.33(b)(3)—List of fatalities and causes of death.
21 CFR 312.33(b)(4)—List of discontinuing subjects.
21 CFR 312.33(b)(5)—Drug action.
21 CFR 312.33(b)(6)—Preclinical studies and findings.
21 CFR 312.33(b)(7)—Significant changes.
21 CFR 312.33(c)—Next year general investigational plan.
21 CFR 312.33(d)—Brochure revision.
21 CFR.312.33(e)—Phase I protocol modifications.
21 CFR.312.33(f)—Foreign marketing developments.
21 CFR 312.38(b) and (c)—Notification of withdrawal of an IND.
21 CFR 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.
21 CFR 312.44(c) and (d)—Opportunity for sponsor response to FDA when IND is terminated.
21 CFR 312.45(a) and (b)—Sponsor request for, or response to, inactive status determination of an IND.
21 CFR 312.47(b)—"End-of-Phase 2" meetings and "Pre-NDA" meetings.
21 CFR 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.
21 CFR 312.54(a) and (b)—Sponsor submissions concerning investigations involving an exception from informed consent under § 50.24.
21 CFR 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.
21 CFR 312.56(b),(c), and (d)—Sponsor monitoring of all clinical investigations, investigators, and drug safety; notification to FDA.
21 CFR 312.58(a)—Sponsor's submission of records to FDA on request.
21 CFR 312.64—Investigator reports to the sponsor.
21 CFR 312.64(a)—Progress reports.
21 CFR 312.64(b)—Safety reports.
21 CFR 312.64(c)—Final reports.
21 CFR 312.66—Investigator reports to Institutional Review Board. Estimates for this requirement are included under § 312.53.
21 CFR 312.70(a)—Investigator disqualification; opportunity to respond to FDA.
21 CFR 312.83—Sponsor submission of treatment protocol. Estimates for this requirement are included under § 312.320.
21 CFR 312.85—Sponsors conducting Phase 4 studies. Estimates for this requirement are included under § 312.23 in 0910–0014, and §§ 314.50, 314.70, and 314.81 in 0910–0001.
21 CFR 312.110(b)—Request to export an investigational drug.
21 CFR 312.120—Submissions related to foreign clinical studies not conducted under an IND.
21 CFR 312.130(d)—Request for disclosable information for investigations involving an exception from informed consent under § 50.24.
21 CFR 312.310(b); 312.305(b)—Submissions related to expanded access and treatment of an individual patient.
21 CFR 312.310(d)—Submissions related to emergency use of an investigational new drug.
21 CFR 312.315(c); 312.305(b)—Submissions related to expanded access and treatment of an intermediate size patient population.
21 CFR 312.320—Submissions related to treatment IND or treatment protocol.

Recordkeeping Requirements

21 CFR 312.52(a)—Transfer of obligations to a contract research organization.
21 CFR 312.57—Sponsor recordkeeping.
21 CFR 312.59—Sponsor recordkeeping of disposition of unused supply of drugs. Estimates for this requirement are included under § 312.57.
21 CFR 312.62(a)—Investigator recordkeeping of disposition of drugs.
21 CFR 312.62(b)—Investigator recordkeeping of case histories of individuals.
21 CFR 312.120(d)—Recordkeeping requirements for submissions related to foreign clinical studies not conducted under an IND. Estimates for this requirement are included under § 312.57.
21 CFR 312.160(a)(3)—Records maintenance: shipment of drugs for investigational use in laboratory research animals or in vitro tests.
21 CFR 312.160(c)—Shipper records of alternative disposition of unused drugs.

In the tables in this document, the estimates for "No. of Respondents," "Annual Frequency per Response," 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 2007 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 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
312.2(e)	455	1.03	469	24	11,256
312.8	30	1.13	34	48	1,632
312.10	4	1	4	10	40
312.23(a) through (f)	2,496	1.26	3,145	1,600	5,032,000
312.30(a) through (e)	2,030	8.91	18,087	284	5,136,708
312.31 (b)	153	2.97	454	100	45,400
312.32(c) and (d)	985	23.06	22,714	32	726,848
312.33(a) through (f)	2,564	2.34	6,000	360	2,160,000
312.38(b) and (c)	654	1.34	876	28	24,528
312.42(e)	149	1.10	164	284	46,576
312.44(c) and (d)	44	1	44	16	704
312.45(a) and (b)	254	1.43	363	12	4,356
312.47(b)	281	1.8	506	160	80,960
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)	985	2,306	2,271,410	48	109,027,680
312.56(b), (c), and (d)	18	1	18	80	1,440
312.58(a)	91	4.10	373	8	2,984
312.64	31,791	1	31,791	24	762,984
312.70(a)	4	1	4	40	160
312.110(b)	23	18.26	420	75	31,500
312.120	115	5	575	32	18,400
312.130(d)	3	1	3	8	24
312.310(b) and 312.305(b)	988	1	988	8	7,904
312.310(d)	525	1.23	646	16	10,336
312.315(c) and 312.305(b)	68	1	68	120	8,160
312.320	9	1.11	10	300	3,000
Total					124,841,100

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

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

21 CFR Section	Number of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
312.52(a)	335	1.5	503	2	1,006
312.57	75	485.28	36,396	100	3,639,600
312.62(a)	14,732	1	14,732	40	589,280
312.62(b)	147,320	1	147,320	40	5,892,800
312.160(a)(3)	547	1.4	766	.5	383
312.160(c)	547	1.4	766	.5	383
Total					10,123,452

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

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

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
312.7(d)	41	1.4	57	24	1,368
312.23(a) through (f) and 312.120(b), (c)(2), and (c)(3)	433	1.3	563	1,808	1,017,904
312.30(a) through (e)	590	6.8	4,012	284	1,139,408
312.31(b)	263	29.3	7,706	100	770,600
312.32(c) and (d) and 312.56(c)	294	13.7	4,028	32	128,896
312.33(a) through (f) and 312.56(c)	647	2.3	1,488	360	535,680
312.35(a) and (b)	1	1	1	300	300
312.36	6	1	6	16	96

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

21 CFR Section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
312.38(b) and (c)	117	1.3	152	28	4,256
312.42(e)	74	1.5	111	284	31,524
312.44(c) and (d)	17	1.1	19	16	304
312.45(a) and (b)	60	1.8	108	12	1,296
312.47(b)	43	1.5	65	160	10,400
312.53(c)	348	6.6	2,297	80	183,760
312.54(a) and (b)	1	1	1	48	48
312.55(b)	138	2.5	345	48	16,560
312.56(b) and (d)	14	1.6	22	80	1,760
312.58(a)	8	1	8	8	64
312.64(a) through (d)	6,003	3.5	21,010	24	504,240
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					4,350,287

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR Section	Number of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
312.52(a)	139	1.4	195	2	390
312.57(a) and (b)	433	2.6	1,126	100	112,600
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	204	0.5	102
312.160(c)	146	1.4	204	0.5	102
Total					2,563,994

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

Dated: January 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1758 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0084]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Pretesting of Tobacco Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitle "Pretesting of Tobacco Communications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *e-mail: Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 2010 (75 FR 47600), 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 0910–0674. The approval expires on January 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: January 21, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1757 Filed 1–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0250]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Premarket Approval of Medical Devices" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@FDA.HHS.GOV.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 24, 2010