under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application (IND) under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

In the **Federal Register** of September 21, 2007 (72 FR 54044), 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	Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3) and (c)(4)	FDA 2914	80	1	80	1	80
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1,190
361.1(d)(8)		50	6.8	340	0.1	34
Total Reporting						1,304

[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-keeping	Hours per Record	Total Hours
361.1(c)(2)	80	4	10	800
361.1(d)(5)	50	6.8	.75	38
Total Recordkeeping				838

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

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23977 Filed 12–10–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0317]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Pharmacogenomic Data Submissions; Extension

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 January 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0557. Also

include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

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.

Guidance for Industry on Pharmacogenomic Data Submissions (OMB Control Number 0910–0557)—Extension

The guidance provides recommendations to sponsors submitting or holding investigational new drugs (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, or BLAs for human drugs and biologics.

Burden Estimate: The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312—INDs); 0910–0001 (part 314—NDAs and annual reports); and 0910–0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, and other, less well developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 8 sponsors will submit approximately 10 VGDSs and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

In the **Federal Register** of August 21, 2007 (72 FR 46636), FDA published a 60-day notice requesting public comment on the information collection provisions. We received one comment which requested clarification of how the confidential information received in a VGDS will remain outside the public domain and not end up being cited in a publicly posted submission review.

FDA Response: Information received as part of a VGDS not to be used for regulatory decisionmaking and received in confidence is covered by the same confidentiality levels of INDs, NDAs, and BLAs. There is no publicly posted submission review associated with the data in a VGDS, and release of information associated with a VGDS is exclusively up to the sponsor of the VGDS and not to FDA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Voluntary Genomic Data Submissions	8	1.25	10	50	500

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

Dated: December 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–23996 Filed 12–10–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0236]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Presubmission Conferences, New Animal Drug Applications and Supporting Regulations and Guidance 152, and Form FDA 356V

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 January 10, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments