EXHIBIT 3—ESTIMATED COST—Continued

Cost component	Total cost	Annualized cost
Data Processing and Analysis	70,569	47,046
Publication of Results	41,420	27,613
Project Management	68,908	45,939
Overhead	76,320	50,880
Total	399,961	266,641

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 30, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E9–537 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

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 February 17, 2009.

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 *oira_submissions@OMB.eop.gov*. All comments should be identified with the OMB control number 0910–0575. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr.,Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR Part 514 (OMB Control Number 0910–0575)—Extension

The Center for Veterinary Medicine has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act of 1988 permitted the generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and the pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: (1) ''USP definition'' approach or (2) ''Dosage adjusted'' approach.

In the **Federal Register** of October 29, 2008 (73 FR 64338), 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 FOR WATER SOLUBLE POWDERS[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	1	1	1	5	5
Same API/solubility approach	5	5	5	10	50
Total burden hours					55

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES[1]

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Same formulation/manufacturing process approach	2	2	2	5	10
Same API/solubility approach	10	10	10	20	200
Total burden hours					210

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

The sources of the previous data are records of generic drug applications over the past 10 years.

Dated: January 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–782 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0202] (formerly Docket No. 2007D–0106)

Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Adverse Event Reporting—Improving Human Subject Protection; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Adverse Event Reporting—Improving Human Subject Protection.'' This guidance is intended to assist the research community in interpreting requirements for submitting reports of unanticipated problems, including certain adverse events reports, to institutional review boards (IRBs). FDA developed this guidance in response to concerns raised by the IRB community that increasingly large volumes of individual, unanalyzed adverse event reports are inhibiting, rather than enhancing, the ability of IRBs to adequately protect human subjects. The guidance provides recommendations to IRBs, sponsors, and investigators on improving the usefulness of the adverse event information submitted to IRBs. Elsewhere in this issue of the **Federal Register**, FDA is issuing the final rule entitled ''Institutional Review Boards; Registration Requirements.''

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2270, e-mail: *Joseph.Griffin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for clinical investigators, sponsors, and IRBs entitled ''Adverse Event Reporting—Improving Human Subject Protection.'' Under the regulations in 21 CFR part 50 (Protection of Human Subjects), part 56 (21 CFR part 56) (Institutional Review Boards), part 312 (21 CFR part 312) (Investigational New Drug Application), and part 812 (21 CFR part 812) (Investigational Device Exemptions), an IRB must review and approve a clinical study before the study is initiated. Additionally, after an IRB's initial review and approval, an IRB must conduct continuing review of the study at intervals appropriate to the degree of risk presented by the study, at least annually. The primary purpose of both the initial review of a study and the periodic review of the conduct of the study is to ensure the protection of the rights and welfare of human subjects. To do its job, an IRB must be informed of any unanticipated problems in the study and any changes in the research activity. This guidance discusses adverse event reporting to IRBs by sponsors and investigators and emphasizes the value of well-analyzed adverse event data to an IRB review.

A notice announcing the draft version of this guidance published in the **Federal Register** on April 9, 2007 (72 FR 17562). After carefully considering all received comments, the agency is finalizing that guidance. The draft and the final have relatively minor substantive differences. The recommendations section in the final