Table 1.—Estimated Annual Reporting Burden for Third Parties

Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
II.C.1–5 (Recognition Requests):							
First Submission	15	0.5[1]	7.5	24	180		
Additional information	8	0.5[1]	4.0	4	16		
Updates	10	1.0	10.0	1	10		
510(k) Reviews							
II.G.1–6	10	50	500	40	20,000	57,250	28,625
Total					20,206	57,250	28,625

[1]These submissions are made in the first year only, the reporting frequency has been averaged over the pilot program's 2-year period to provide an annual frequency.

Table 2.—Estimated Annual Recordkeeping Burden

Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
II.J.	10	252	2,520	63	630		

Capital costs and operating and maintenance costs are attributable to reporting and are included in the table above.

Organizations and individuals may submit comments regarding this information collection, including suggestions for reducing this burden, by June 3, 1996, and should direct them to the Dockets Management Branch (address above).

Dated: March 25, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–8149 Filed 4–1–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in November 1995. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting is currently scheduled for June 1996. Drug companies may submit review requests for the June meeting before May 3, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Janet M. Jones, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane (WOC II rm. 6020), Rockville, MD 20857, 301–594–5445.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and, in phases 2, 3, and 4 of drug development, to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may

be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations at § 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold. In CDER, a clinical hold is ordered by the director of the new drug division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 5 working days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 5 working days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

FDA regulations at § 312.48 and CDER's Manual of Policies and Procedures (MAPP 6030.1) provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds.

One initiative undertaken by FDA was the establishment of a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a manner that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending hold to have that hold considered ''anonymously.'' The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and the FDA Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in November 1995.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CDER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER policy.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, will be available through the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its June meeting. Submissions should be made by May 3, 1996, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Revision of a currently approved collection; *Title of Information Collection:* Statistical Report on Medical Care: Eligibles, Recipients, Payments and Services; *Form No.:* HCFA–2082; *Use:* The data reported in the HCFA–2082 are the basis of actuarial forecasts for Medicaid service utilization and costs; of analyses and cost savings estimates required for legislative initiatives relating to Medicaid and for responding to requests for information from HCFA components, the Department, Congress and other customers; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 54; *Total Annual*