Federal funds for all four project years (based on an award of $100,000 per budget year), must include a match of at least $44,444 (10 percent of total approved project costs, *i.e.,* $11,111 per budget period).

Anticipated Number of Projects to be Funded: It is anticipated that two to three projects will be funded.

Evaluation Criteria

Reviewers will consider the following factors when scoring applications. However, in order to adequately prepare their applications, applicants must refer to the full program announcement for the specific evaluation criteria for each priority area. The points awarded for each criterion vary, depending on the specific priority area.

Criterion 1: Objectives and Need for Assistance

Applications will be judged on the extent to which they clearly specify the purposes and/or strategies of the proposed project and their relationship to legislative authority and child welfare outcomes, as appropriate; the quality of their statement regarding the need for the project; and evidence that the applicant understands current issues and recent developments in the field that may have relevance to the implementation of the project. Applicants must refer to the specific evaluation criteria for each priority area contained in the full Program Announcement in order to adequately prepare their applications. The points awarded for this criterion vary, depending on the specific priority area.

Criterion 2: Results or Benefits Expected

Applications will be judged on the extent to which they define both interim and final results and benefits that they will seek to achieve through implementation of their proposed projects, how these results/benefits will contribute to the overall improvement of the field, and, where appropriate, the innovative aspects of the proposed project. Applicants are encouraged to define clear, objective measures by which their results/benefits will be determined. Applicants must refer to the specific evaluation criteria for each priority area contained in the full Program Announcement in order to adequately prepare their applications. The points awarded for this criterion vary, depending on the specific priority area.

Criterion 3: Approach

Applicants will be judged on the clarity, feasibility, and thoroughness of their description of the approach that they intend to use in implementing proposed projects. The approach sections will be expected to include, as appropriate, information on barriers to implementation and proposed solutions to those barriers; necessary collaborations with other organizations and agencies and their respective roles; evaluation plans; reporting requirements; and staffing plans. Applicants must refer to the specific evaluation criteria for each priority area contained in the full Program Announcement in order to adequately prepare their applications. The points awarded for this criterion vary, depending on the specific priority area.

Criterion 4: Organization Profile

Applicants will be judged on the experience and demonstrated competence of staff who are proposed to implement the project and, as appropriate, the experience of the organization in implementing related projects. Applicants must refer to the specific evaluation criteria for each priority area contained in the full Program Announcement in order to adequately prepare their applications. The points awarded for this criterion vary, depending on the specific priority area.

Criterion 5: Budget and Budget Justification

Applicants will be judged on the adequacy, reasonableness, and completeness of their budget requests to support their proposed projects, including their management plans to control and account for expenditure of project funds. Applicants must refer to the specific evaluation criteria for each priority area contained in the full Program Announcement in order to adequately prepare their applications. The points awarded for this criterion vary, depending on the specific priority area.

Required Notification of the Single Point of Contact

Most portions of this program are covered under Executive Order 12372, Intergovernmental Review of Federal Programs, and 45 CFR part 100, Intergovernmental Review of Department of Health and Human Services Program and Activities. Under the Order, States may design their own process for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Colorado, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Palau, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, and American Samoa have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-three jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Applicants to the Adoption Opportunities program are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations.

Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the accommodate or explain rule. A list of the Single Points of Contact for each State and Territory can be found on the web site *http://www.dhhs.gov/progorg/grantsnet/laws-reg/spoq0695.htm.*

Dated: April 7, 2000.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 00–9150 Filed 4–12–00; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1224]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry: Submitting and Reviewing Complete Responses to Clinical Holds

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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in a guidance for industry entitled ''Submitting and Reviewing Complete Responses to Clinical Holds.'' The guidance describes how to submit a complete response if an investigational new drug (IND) application is placed on clinical hold by FDA.

DATES: Submit written comments on the collection of information by June 12, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: 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: 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, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (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.

Guidance for Industry: ''Submitting and Reviewing Complete Responses to Clinical Holds''

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105–115). Section 117 of the Modernization Act provides that a written request to FDA from the applicant of an investigation that a clinical hold be removed shall receive a decision in writing, specifying the reasons for that decision, within 30 days after receipt of such request. A clinical hold is an order issued by FDA to the applicant to delay a proposed clinical investigation or to suspend an ongoing investigation for a drug or biologic. An applicant may respond to a clinical hold.

Under section 505(i)(3)(C) of the Federal Food, Drug, and Cosmetic Act, any written request to FDA from the sponsor of an investigation that a clinical hold be removed must receive a decision, in writing and specifying the reasons, within 30 days after receipt of the request. The request must include sufficient information to support the removal of the clinical hold.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice of availability of a guidance that described how applicants should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to respond. FDA is now issuing a revised guidance.

The revised guidance states that FDA will respond in writing within 30-calendar days of receipt of a sponsor's request to release a clinical hold and a complete response to the issue(s) that led to the clinical hold. An applicant's complete response to an IND clinical hold is a response in which all clinical hold issues identified in the clinical hold letter have been addressed.

The guidance requests that applicants type in large, bold letters at the top of the cover letter of the complete response ''Clinical Hold Complete Response'' to expedite review of the response. The guidance also requests that applicants submit the complete response letter in triplicate to the IND, and that they fax a copy of the cover letter to FDA's contact listed in the clinical hold letter who is responsible for the IND. The guidance requests more than an original and two copies of the cover letter in order to ensure that the submission is received and handled in a timely manner.

Based on data concerning the number of complete responses to clinical holds received by the Center for Drug Evaluation and Research (CDER) from July 1, 1998, to June 30, 1999, CDER estimates that approximately 48 responses are submitted annually from approximately 43 applicants, and that it takes approximately 284 hours to prepare and submit to CDER each response.

Based on data concerning the number of complete responses to clinical holds received by the Center for Biologics Evaluation and Research (CBER) in fiscal year 1999, CBER estimates that approximately 134 responses are submitted annually from approximately 110 applicants, and that it takes approximately 284 hours to prepare and submit to CBER each response.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Complete Responses to Clinical Holds	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	43	1	48	284	13,632
CBER	110	1	134	284	38,056
Total					51,688

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

Dated: April 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–9128 Filed 4–12–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1226]

Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational Device Exemptions, Reports, and Records

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for investigational device exemptions (IDE's).

DATES: Submit written comments on the collection of information by June 12, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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: (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 Device Exemptions, Reports, and Records—21 CFR Part 812 (OMB Control No. 0910–0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The FDA Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an IDE supplement.

An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices, and allow investigators the maximum freedom possible, without jeopardizing the health and safety of the public or violating ethical standards.

To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety, or welfare of human subjects, are subject to the full requirements of the IDE regulation. Nonsignificant risk device investigations, ones that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements.

The regulation also includes provisions for treatment IDE's. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available.

Section 812.10 allows the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety.

Sections 812.20, 812.25, and 812.27, consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations. Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in this original IDE application is evaluated by the Center for Devices and Radiological Health to determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE.

Once FDA approves an IDE application, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation which affects the scientific soundness of the study or the rights, safety, or welfare of the subjects is required to submit a request for the change to FDA. Under § 812.150, a sponsor is required to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to ensure