12862 in the Administration for Children and Families.

OMB No. 0980–0266.

Description: Under the provisions of the Federal Paperwork Reduction Act of 1995 (Pub. L. 104–13), the Administration for Children and Families (ACF) is requesting clearance for instruments to implement Executive Order 12862 within the ACF. The purpose of the data collection is to obtain customer satisfaction information from those entities who are funded to be our partners in the delivery of services to the American public. ACF partners are those entities that receive funding to deliver services or assistance from ACF programs. Examples of partners are States and local governments, territories, service providers, Indian Tribes and Tribal organizations, grantees, researchers, or other intermediaries serving target populations identified by and funded directly or indirectly by ACF. The surveys will obtain information about how well ACF is meeting the needs or our partners in operating the ACF programs.

Respondents: State, Local, Tribal Govt. or Not-for-Profit Institutions

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Governments	51	10	1	510
Head Start grantees & Delegates	200	1	.5	100
Other Discretionary Grant Programs	200	10	.5	1,000
Indian Tribes & tribal Organizations	25	10	.5	50
Estimated Total Annual Burden Hours: 1,660				

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment in the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the qualify, utility, and clarify of the information to be collected; and (d) ways to minimize the burden of the collection on information on respondents, including through the use of automated collection techniques or other forms on information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 13, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–13112 Filed 5–15–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0513]

Agency Information Collection Activities; Orphan Drugs: Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by June 17, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs—21 CFR Part 316—(OMB No. 0910–0167—Reinstatement)

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd), give FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs; (2) designate eligible drugs as orphan drugs; (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval; and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and set forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug

application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining ophan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers. FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total Burden Hours	.....	.....	.....	.....	20,964

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 5 years, that 90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13042 Filed 5–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0286]

Environmental Assessments and Findings of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has reviewed environmental assessments (EA's) and issued findings of no significant impact (FONSI's) relating to the 167 new drug applications (NDA's) and supplemental applications listed in this document. FDA is publishing this notice because Federal regulations require public notice of the availability of environmental documents.

ADDRESSES: The EA's and FONSI's may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, or a copy may be requested by writing the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5629.

SUPPLEMENTARY INFORMATION: Under the National Environmental Policy Act of 1969 (NEPA), Congress declared that it will be the continuing policy of the Federal Government to ''use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic and other requirements of present and future generations of Americans.'' (See 42 U.S.C. 4331(a).) NEPA requires all Federal agencies to include in every proposal for major Federal actions significantly affecting the quality of the human environment, a detailed statement assessing the environmental impact of, and alternatives to, the proposed action and to make available to the public such statements. (See 42 U.S.C. 4332, 40 CFR 1506.6, and 21 CFR 25.51(b).)

FDA implements NEPA through its regulations in part 25 (21 CFR part 25). Under those regulations, actions to approve NDA's, abbreviated new drug applications (ANDA's), and supplements to existing approvals ordinarily require the preparation of an EA. (See § 25.20(l).)

FDA approved 167 NDA's and supplemental NDA's and ANDA's for the products listed in the following table: