testimonials from consumers appearing in the advertisements for Cholestaway reflect the typical or ordinary experience of members of the public who use the product. The complaint alleges that the respondents did not have a reasonable basis for any of these representations at the time they were made.

The consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the order prohibits the respondents from making the representations challenged in the complaint, unless they possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part II prohibits respondents from making any representations about the efficacy, performance, safety or benefits of any food, dietary supplement of drug unless they possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part III prohibits the respondents from mispresenting the existence, contents, validity, results, conclusions or interpretations of any test, study, or research.

Part IV prohibits the respondents from representing that the experience represented by a user testimonial or endorsement of the product is the typical or ordinary experience of users of the product unless the representation is substantiated or they disclose what the generally expected results would be or that consumers should not be expect the same results.

Part V allows the respondents to make respondentations for any drug that are permitted in labeling for that drug under any tentative final or final Food and Drug Administration (''FDA'') standard or under any new drug application approved by the FDA.

Part VI allows the respondents to make representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts VII through X require the respondents to keep copies of advertisements making representations covered by the order; to keep records concerning those representations, including materials that they relied upon making the representations; to provide copies of the order to certain of the respondents' personnel; to notify the Commission of changes in corporate structure; and to file complaint reports with the Commission. Part XI provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and its is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–13142 Filed 5–15–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Financial Status Reporting Form (SF–269) with Supplemental Form (ADD–02) for Developmental Disabilities Council Program.

OMB No.: 0980–0212.

Description: Developmental Disabilities Council Program funds are awarded contingent on fiscal requirements in Part B of the Developmental Disabilities Assistance and Bill of Rights Act. The SF–269, mandated in the revised OMB Circular A–102, provides no breakouts necessary for proper stewardship. The proposed alternative would breakout the necessary information, but would do so in a consolidated manner that makes reporting easier. It will allow proactive compliance monitoring by the Government to catch problems early.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of respondents per respondent	Average burden hours per response	Total burden hours
ADD–02	55	2	90	990
Estimated Total Annual Burden Hours: 990				

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 on 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 quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of 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. 98–13111 Filed 5–15–98; 8:45 am]

BILLING CODE 4104–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Voluntary Surveys of Program Partners to Implement Executive Order

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