D. Management Plan and Project Goals and Objectives—25 Points. This includes: 1. The management work plan for conducting the project including the process (approach and methods) by which the applicant will meet established goals and objectives.

2. The presentation of those specific goals, objectives and timelines (with performance expectations for the first year by calendar month or quarter, and a work plan outline for the second, third, and fourth years of the project).

3. The description of the major tasks and responsibilities for key positions including the applicant organization and identified contractual/consultant personnel (include an organization chart and denote the relationship of this project within the applicant organization).

4. The methods by which the applicant will seek out, utilize, and benefit from input by persons with disabilities and their families, and from organizations representing the disability and physical activity communities in planning for project priorities and activities.

5. The description of how the applicant will evaluate its work plan and all informational, referral, communications, and technical assistance activities.

E. Budget Justification—Not Scored. This criteria includes the adequacy of the budget justification and its relationship to program operations, collaborations, and services. Each line item of the budget must be well justified in a brief narrative with special attention given to contractual requests including the responsibilities of consultants, percentage time equivalents, hourly or daily rates, etc. This section will also be evaluated on the adequacy of facilities to conduct the project. The relevance of this section to the other evaluation criteria will be measured on the extent to which the budget narrative is reasonable, clearly documented, accurate, and consistent with the purpose of this announcement.

F. Human Subjects—Not Scored. This includes the extent to which the application adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects. If the proposed project involves research on human participants, assurance and evidence must be provided that the project will be subject to initial and continuous reviews by an appropriate institutional review board. Does the applicant adequately address the requirements of 45 CFR 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of: 1. Semi-annual progress reports; due dates to be denoted in the notice of grant award;

2. Financial status report, due no more than 90 days after the end of each budget period; and

3. Final financial status and performance reports, due no more than 90 days after the end of the project period.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I.

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under the Public Health Service Act, Section 301(a) [42 U.S.C. section 241(a), as amended. The Catalog of Federal Domestic Assistance number is 93.184.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement Number of interest. Also, the CDC Home Page on the Internet: http://www.cdc.gov is available for copies of this Announcement, application forms and funding information.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99010, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE, Mailstop E–13, Atlanta, GA 30305–2209, telephone (404) 842–6804. E-mail address: vxw1@cdc.gov.

For program technical assistance, contact Joseph B. Smith, Office on Disability and Health, National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention, 4770 Buford Highway, Mailstop F–29, Atlanta, GA, telephone (770) 488–7082. E-mail address: jos4@cdc.gov

Dated: November 4, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–30060 Filed 11–9–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Federal Allotments to States for Social Services Expenditures, Pursuant to Title XX, Block Grants to States for Social Services; Promulgation for Fiscal Year 2000

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notification of allocation of title XX—social services block grant allotments for Fiscal Year 2000.

SUMMARY: This issuance sets forth the individual allotments to States for Fiscal Year 2000, pursuant to title XX of the Social Security Act, as amended (Act). The allotments to the States published herein are based upon the authorization set forth in section 2003(c) of the Social Security Act and are contingent upon Congressional appropriations for the fiscal year. If Congress enacts and the President approves an amount different from the authorization, the allotments will be adjusted proportionately.

FOR FURTHER INFORMATION CONTACT: John K. Jolley, (202) 401–5284.

SUPPLEMENTARY INFORMATION: Section 2003(c) of the Act authorizes $2.380 billion for Fiscal Year 2000 and provides that it be allocated as follows:

(1) Puerto Rico, Guam, the Virgin Island, and the Northern Mariana Islands each receives an amount which bears the same ratio to $2.380 billion as its allocation for Fiscal Year 1981 bore to $2.9 billion.

(2) American Samoa receives an amount which bears the same ratio to the amount allotted to the Northern Mariana Islands as the population of American Samoa bears to the population of the Northern Mariana Islands determined on the basis of the most recent data available at the time such allotment is determined.

(3) The remainder of the $2.380 billion is allotted to each State in the same proportion as that State's population is to the population of all

States, based upon the most recent data available from the Department of Commerce. For Fiscal Year 2000, the allotments are based upon the Bureau of Census population statistics contained in its reports ''Population of States by Broad Age Groups and Sex: 1990 and 1995 (CB96–88, Table 4) released May 31, 1996, and ''1990 Census of Population and Housing'' (CPH–6–AS and CPH–6–CNMI) published April 1992, which was the most recent data available from the Department of Commerce at the time of the Department's initial promulgation.

EFFECTIVE DATE: The allotments are effective October 1, 1999.

FISCAL YEAR 2000 FEDERAL ALLOTMENTS TO STATES FOR SOCIAL SERVICES—TITLE XX BLOCK GRANTS

Alabama	$38,307,808	$37,004,055
Alaska	5,440,375	5,255,219
American Samoa	88,560	85,546
Arizona	37,992,554	36,699,530
Arkansas	22,373,994	21,612,526
California	284,529,822	274,846,246
Colorado	33,750,142	32,601,503
Connecticut	29,498,723	28,494,775
Delaware	6,458,194	6,238,398
Dist. of Col	4,990,013	4,820,185
Florida	127,596,615	123,254,041
Georgia	64,861,162	62,653,702
Guam	410,345	396,379
Hawaii	10,691,598	10,327,724
Idaho	10,475,425	10,118,909
Illinois	106,555,694	102,929,219
Indiana	52,269,036	50,490,132
Iowa	25,598,587	24,727,374
Kansas	23,103,580	22,317,282
Kentucky	34,767,961	33,584,682
Louisiana	39,109,452	37,778,416
Maine	11,177,990	10,797,562
Maryland	45,423,530	43,877,603
Massachusetts	54,709,999	52,848,020
Michigan	86,010,171	83,082,934
Minnesota	41,523,394	40,110,202
Mississippi	24,292,536	23,465,773
MissourI	47,954,566	46,322,499
Montana	7,836,302	7,569,604
Nebraska	14,744,858	14,243,037
Nevada	13,781,083	13,312,063
New Hampshire	10,340,316	9,988,397
New Jersey	71,562,552	69,127,020
New Mexico	15,177,206	14,660,671
New York	163,355,373	157,795,800
North Carolina	64,807,119	62,601,499
North Dakota	5,773,643	5,577,145
No. Mariana Islands	82,069	79,276
Ohio	100,439,775	97,021,447
Oklahoma	29,525,745	28,520,877
Oregon	28,291,753	27,328,883
Pennsylvania	108,735,447	105,034,787
Puerto Rico	12,310,345	11,891,379
Rhode Island	8,917,171	8,613,687
South Carolina	33,083,606	31,957,651
South Dakota	6,566,281	6,342,807
Tennessee	47,342,073	45,730,851
Texas	168,651,632	162,911,808
Utah	17,573,133	16,975,056
Vermont	5,269,238	5,089,907
Virgin Islands	410,345	396,379
Virginia	59,609,939	57,581,197
Washington	48,918,341	47,253,473
West Virginia	16,465,242	15,904,870
Wisconsin	46,144,110	44,573,659
Wyoming	4,323,477	4,176,334
Total	2,380,000,000	2,299,000,000

Dated: November 3, 1998.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 98–30075 Filed 11–9–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Proposed Collection; MedWatch: The FDA Medical Products Reporting Program; Comment Request

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 revision of two forms for 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 proposed revision of two forms from ''MedWatch: The FDA Medical Products Reporting Program'' (MedWatch). These forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), will be used to report to the agency on adverse events and product problems that occur with all medical products regulated by FDA.

DATES: Submit written comments on the collection of information by January 11, 1999.

ADDRESSES: Submit written requests for single copies of the revised MedWatch reporting forms, Form FDA 3500 (voluntary) and Form FDA 3500A (mandatory), and a summary of the proposed revisions to the forms, by e-mail to ''medwatch@oc.fda.gov'', by fax to 301–827–7241, or by mail to ''MedWatch: The FDA Medical Product Reporting Program,'' Food and Drug Administration (HF–2), 5600 Fishers Lane, rm. 17–65, Rockville, MD 20857 (301–827–7240). Requests by mail should include one self-addressed adhesive label to assist that office in processing your request. Copies of the forms and the summary of the changes may also be obtained via Internet at ''http://www.fda.gov/medwatch'' under ''How to Report''.

Submit written comments on the revised MedWatch reporting forms to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION:

I. Background

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 revision 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 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.

MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) (OMB Control Number 0910–0291—Revision)

Under sections 505, 507, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 357, 360b, 360c, 360e, and 393); and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (21 U.S.C. 301), section 402 of the act (21 U.S.C. 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information, will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through regulatory action ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with all medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used. Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events and product problems by health professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation). Respondents to this collection of information are health professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, distributors, and importers.

II. Use of the Voluntary Version (FDA Form 3500):

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the agency or the manufacturer. There is one exception. The National Childhood Injury Act of 1986 mandates that certain adverse reactions following immunization be reported by physicians to the joint FDA/Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS).