DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Agency Information Collection Activities: Submission for Office of Management and Budget (OMB) Review; Comment Request; Extension

AGENCY: Administration on Aging, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging is announcing an opportunity for public comment on the continued collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish in the **Federal Register** concerning each collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements relating to the submission, by AoA grantees, of semiannual financial reports on all Title III grants. The information contained in the OMB 269 and its supplemental forms reports currently being collected concurrently.

SUPPLEMENTARY INFORMATION:

Title: Supplemental Form to the Financial Status Report for all AoA Title II Grantees.

Description: Supplemental Form to the Financial Status Report provide an understanding of how projects funded by the Older Americans Act are being administered by grantees, in conformance with legislative requirements, pertinent federal regulations, and other applicable instructions and guidelines issued by the Administration on Aging (AoA). This information will be used for federal oversight of Title III Projects.

Respondents: State Agencies on Aging.

Number of Respondents: 57.

Average Number of Responses per Respondent: 2.

Average Burden Hours: ½ hour per State Agency.

Additional Information

Copies of the collection may be obtained by writing to the Administration on Aging, Office of the Executive Secretariat, 330 Independence Avenue, SW, Washington, DC 20201, Attn: AoA Reports Clearance Officer.

OMB Comment

OMB is required to make a decision, concerning the collection of information, between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 10 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following address: Administration on Aging, Wilbur J. Cohen Federal Building, 330 Independence Avenue, SW, Washington, D.C. 20201 ATTN: Margaret A. Tolson.

Dated: November 14, 1997.

William F. Benson,

Acting Principal Deputy Assistant Secretary on Aging.

[FR Doc. 97–30567 Filed 11–20–97; 8:45 am]

BILLING CODE 4150–04–M

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 1999

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 1999.

SUMMARY: This issuance sets forth the individual allotments to States for Fiscal Year 1999, 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 of the 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: Frank A. Burns, (202) 401–5536.

SUPPLEMENTARY INFORMATION: Section 2003 of the Act authorizes $2.380 billion for Fiscal Year 1999 and provides that it be allocated as follows:

(1) Puerto Rico, Guam, the Virgin Islands, 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 1999, the allotments are based upon the Bureau of Census population statistics contained in its report ''Estimates of the Population of the U.S. Regions, and States by Selected Age Groups and Sex: 1990 to 1996 (CB97–64, released April 21, 1997), and ''1990 Census of Population and Housing'' (CPH–6–AS and CPH–6–CNMI) published April 1992, which are the most recent data available from the Department of Commerce at this time as to the population of each State and each Territory.

EFFECTIVE DATE: The allotments shall be effective October 1, 1998.

FISCAL YEAR 1999 FEDERAL ALLOTMENTS TO STATES FOR SOCIAL SERVICES—TITLE XX BLOCK GRANTS

Total	$2,380,000,000
ALABAMA	38,121,040
ALASKA	5,415,275
AMERICAN SAMOA	88,560
ARIZONA	39,503,853
ARKANSAS	22,392,654
CALIFORNIA	284,395,631
COLORADO	34,106,421
CONNECTICUT	29,208,585
DELAWARE	6,467,998
DIST. OF COLUMBIA	4,844,307
FLORIDA	128,467,816
GEORGIA	65,598,878
GUAM	410,345
HAWAII	10,562,909
IDAHO	10,607,516
ILLINOIS	105,691,543
INDIANA	52,109,758
IOWA	25,443,765
KANSAS	22,945,779
KENTUCKY	34,650,625
LOUISIANA	38,816,907
MAINE	11,089,270
MARYLAND	45,249,220
MASSACHUSETTS	54,349,023
MICHIGAN	85,591,682
MINNESOTA	41,555,770
MISSISSIPPI	24,230,457
MISSOURI	47,809,654
MONTANA	7,841,890
NEBRASKA	14,738,113
NEVADA	14,300,966
NEW HAMPSHIRE	10,366,639
NEW JERSEY	71,263,952
NEW MEXICO	15,282,317
NEW YORK	162,235,224
NORTH CAROLINA	65,331,237

FISCAL YEAR 1999 FEDERAL ALLOTMENTS TO STATES FOR SOCIAL SERVICES—TITLE XX BLOCK GRANTS—Continued

NORTH DAKOTA	5,745,366
NO. MARIANA ISLANDS	82,069
OHIO	99,678,535
OKLAHOMA	29,449,462
OREGON	28,584,089
PENNSYLVANIA	107,556,110
PUERTO RICO	12,310,345
RHODE ISLAND	8,832,162
SOUTH CAROLINA	33,000,170
SOUTH DAKOTA	6,530,447
TENNESSEE	47,461,721
TEXAS	170,648,082
UTAH	17,842,752
VERMONT	5,254,691
VIRGIN ISLANDS	410,345
VIRGINIA	59,550,185
WASHINGTON	49,361,974
WEST VIRGINIA	16,290,433
WISCONSIN	46,034,301
WYOMING	4,291,182

Dated: November 5, 1997.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 97–30686 Filed 11–20–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0446]

Determination That Desmopressin Acetate Nasal Solution 0.01% (for Refrigerated Storage) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that desmopressin acetate (DDAVP Nasal Spray) nasal solution 0.01% (for refrigerated storage) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for desmopressin acetate nasal solution 0.01% (for refrigerated storage).

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments) that authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

In accordance with § 314.161(a)(1) and (e), the agency initiated procedures to determine whether desmopressin acetate nasal solution 0.01% (for refrigerated storage) was withdrawn from sale for reasons of safety or effectiveness. Desmopressin acetate (DDAVP Nasal Spray) nasal solution 0.01% is the subject of approved NDA 17–922 held by Rhone-Poulenc Rorer Pharmaceuticals, Inc. The original formulation of desmopressin acetate nasal solution 0.01% (NDA 17–922) provided for refrigerated storage of the product. On August 7, 1996, FDA approved Rhone-Poulenc Rorer Pharmaceutical, Inc.'s supplemental application providing for reformulation of desmopressin acetate nasal solution 0.01% for room temperature storage. Rhone-Poulenc Rorer Pharmaceutical, Inc., later withdrew the original formulation, citing easier storage and convenience with the reformulated product.

FDA has reviewed its records and, under § 314.161, has determined that desmopressin acetate nasal solution 0.01% (for refrigerated storage) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain desmopressin acetate nasal solution 0.01% (for refrigerated storage) in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to desmopressin acetate nasal solution 0.01% (for refrigerated storage) may be approved by the agency.

Dated: November 14, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30614 Filed 11-20-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0289]

Content and Format of Labeling for Human Prescription Drugs; Pregnancy Labeling; Public Hearing; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period following its September 12, 1997, public hearing until January 12, 1998. This public hearing, which was announced in the **Federal Register** of July 31, 1997 (62 FR 41061), focused on requirements for the content and format of the pregnancy subsection of labeling for human prescription drugs. The comment period closed on November 12, 1997. This action is being taken in response to the request of the Pharmaceutical Research and Manufacturers of America for additional time to prepare comments because of the complexity and importance of the issues raised by pregnancy labeling.

DATES: Written comments by January 12, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug