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Determination That Desmopressin Acetate Nasal Solution 0.01% (for Refrigerated Storage) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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its determination that desmopressin acetate (DDAVP Nasal Spray) nasal solution 0.01% (for refrigerated storage) was not withdrawn from sale for reasons of safety or effectiveness.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

Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 31, 1997 (62 FR 41061), FDA announced that it would be holding a public hearing on September 12, 1997, concerning the requirements for the content and format of the pregnancy subsection of labeling for human prescription drugs. The public hearing was intended to elicit comments on the practical utility, effects, and limitations of the current pregnancy labeling categories in order to help the agency identify the range of problems associated with the categories and to identify and evaluate options that might address identified problems. Interested persons were given until November 12, 1997, to submit written comments on these issues. Because of the complexity and importance of the issues raised by pregnancy labeling, the Pharmaceutical Research and Manufacturers of America has requested an additional 60 days to prepare comments.

Interested persons may, on or before January 12, 1998, submit to the Dockets Management Branch (address above) written comments on this subject. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket No. 97N–0289. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 13, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30561 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral Drugs Advisory Committee; Notice of Subcommittee Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Subcommittee meeting of the Antiviral Drugs Advisory Committee on immunosuppressive drugs.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on January 14, 1998, 8:30 a.m. to 5 p.m.

Location: Quality Suites, Potomac Ballroom, Three Research Ct., Rockville, MD.

Contact Person: Rhonda W. Stover or John B. Schupp, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On January 14, 1998, the subcommittee will discuss new drug application (NDA) 50–722, CellCept® (mycophenolate mofetil), Syntex, USA, Inc., for immunosuppression following cardiac transplantation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 7, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 7, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 14, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–30705 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on December 11, 1997, 8 a.m. to 6 p.m., and December 12, 1997, 8 a.m. to 3:30 p.m.

Location: DoubleTree Hotel, Plazas I, II, and III, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 11, 1997, the committee will discuss and provide recommendations on the issue of FDA's donor deferral policy regarding men who have had sex with another man even one time since 1977.

On the morning of December 12, 1997, the committee will sit as a medical device panel and make recommendations on the issue of in vitro diagnostic detection of human immunodeficiency virus (HIV) viral load, sponsor, Roche Molecular Systems. In the afternoon, the Committee will hear an informational presentation on hepatitis C virus (HCV) risk in sexual partners of positive individuals.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 4:30 p.m., on December 11, 1997, and between approximately 10 a.m. and 11 a.m. and 2 p.m. and 3 p.m., on December 12, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and