

FISCAL YEAR 1999 FEDERAL ALLOT-
MENTS 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Withdrawn From Sale for Reasons of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its determination that desmopressin acetate (DDAVP Nasal Spray) nasal solution 0.01% (for refrigerated storage) was not withdrawn from sale for reasons of safety or effectiveness.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.*

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**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