

Dated: December 1, 1999.

**Nancy Cheal,**

*Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention.*

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## 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 2001

**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 2001.

**SUMMARY:** The allotments to States for Fiscal Year 2001 are based upon the authorization set forth in section 2003(c) 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. The individual allotments will be available December 15, 1999 on the ACF homepage on the internet: <http://www.acf.dhhs.gov/programs/ocs/ssbg>.

Future notification of allotments for SSBG will no longer be published in the **Federal Register**, but will be available on the internet address given above by December 1st of each succeeding year.

**FOR FURTHER INFORMATION CONTACT:** Margaret Washnitzer, (202) 401-2333.

**SUPPLEMENTARY INFORMATION:** The allotments For Fiscal Year 2001 are based upon the Bureau of Census population statistics contained in its report "Estimates of the Population of States. Annual Time Series, July 1, 1990 to July 1, 1998" (Press Release CB98-242, December 31, 1998), 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, 2000.

Dated: December 1, 1999.

**Donald Sykes,**

*Director, Office of Community Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 99M-1521, 99M-1980, 99M-1696, 99M-1981, 99M-2028, 99M-1520, 99M-1982, 99M-0150, 99M-0255, 99M-2016, 99M-2015, 99M-0871, 99M-0870, 99M-1851]

#### Medical Devices; Availability of Safety and Effectiveness Summaries for PMA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket application (PMA) approvals. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

**ADDRESSES:** Summaries of safety and effectiveness are available on the Internet at <http://www.fda.gov/cdrh/pmepage.html>. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

**FOR FURTHER INFORMATION CONTACT:** Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to

revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet at <http://www.fda.gov>; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMA's and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from April 1, 1999, through June 30, 1999. There were no denial actions during this period. The list provides the manufacturer's name, the generic name or the trade name, and the approval date.