agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

Description of Respondents: Manufacturers of Substances Used in Food and Feed.

In the **Federal Register** of December 17, 1999 (64 FR 70714 at 70715), the agency requested comments on the proposed collections of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	50	1	50	150	7,500
570.36	10	1	10	150	1,500
Total					9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
170.36(c)(1)(v)[2]	50	1	50	15	750
570.36(c)(1)(v)[2]	10	1	10	15	150
Total					900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Due to a clerical error, the CFR cites that appeared in table 2 of the FEDERAL REGISTER of December 17, 1999 (64 FR 70714) were incorrect. Table 2 of this document contains the correct CFR cite.

The reporting requirement is for a proposed rule that has not yet been issued as a final rule. In developing the proposed rule, FDA solicited input from representatives of the food industry on the reporting requirements, but could not fully discuss with those representatives the details of the proposed notification procedure. FDA received no comments on the agency's estimate of the hourly reporting requirements, and thus has no basis to revise that estimate at this time. During 1998, FDA received 12 notices that were submitted under the terms of the proposed rule; between January 1, 1999, and November 30, 1999, FDA received 23 notices. To date, the number of annual notices is less than FDA's estimate; however, the number of annual notices could increase when the proposed rule becomes final.

Dated: March 24, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7933 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M–1031 and 00M–1032]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; List of Premarket Approval Actions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval application (PMA) approvals. This list is intended to inform the public of the existence and the availability of summaries of safety and effectiveness 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/cber/appr1999/1999approv.htm. 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: Nathaniel L. Geary, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

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 the PMA approvals 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 the PMA applications reviewed within CBER, for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure as explained previously through September 30, 1999. There were no denial actions during this period. The list is in order by PMA number and provides the manufacturer's name, the generic name or trade name, and the approval date.

TABLE 1.—LIST OF APPROVAL PMA'S FROM JULY 2, 1999, THROUGH SEPTEMBER 30, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
BP 97–0001/01/00M–1031	Nexell Therapeutics, Inc.	Isolex 300 Magnetic Cell Selection System and Isolex 300i Magnetic Cell Selection System	July 2, 1999
BP 97–0003/00M–1032	Dendreon Corp.	DACS™SC	July 23, 1999

Dated: March 23, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7935 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

State Planning Grants

AGENCY: Health Resources and Services Administration.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces the availability of $15 million to support up to10 State grants for the development of plans to provide access to health insurance coverage for all State residents. This funding has been appropriated under the Fiscal Year (FY) 2000 HHS Appropriations Act.

In FY 2000, HRSA, through its State Planning Grants Program (SPG), will accept applications from States for fiscal year (FY 2000) grants to conduct a one year, in-depth analysis and related activities necessary to develop the most effective methods for providing access to affordable health insurance coverage to all its citizens. States will be expected to design approaches that provide affordable health insurance benefits similar in scope to the Federal Employees Health Benefit Plan, Medicaid, coverage offered to State employees or other similar quality benchmarks. Each State receiving such grants must submit the study and analysis results in the form of a report to the Secretary that identifies the characteristics of the uninsured within the State and proposals for providing them with access to health insurance coverage. Together, these reports will provide additional data about the characteristics of the uninsured generally and potential models for other States seeking to provide comprehensive coverage.

DATES: The time line for application submission, review, and award is follows:

April 10, 2000—Application kits (PHS 5161, OMB 0920–0528) and additional guidance will be available through the HRSA Grants Application Center (GAC). To receive a complete application kit, contact the GAC at 1–877–HRSA–123.

April 26 and 28, 2000—Two pre-application workshops are anticipated at Denver, CO (April 26, 2000) and Philadelphia, PA (April 28, 2000). For more information concerning these workshops, contact the State Planning Grant Program Office at 301–443–4619.

July 10, 2000—Applications due.

August 1–4, 2000—Applications reviewed.

September 30, 2000—Grant awards announced.

ADDRESSES: To receive a complete application kit (*i.e.,* application instructions, necessary forms, and application review criteria), contact the HRSA GAC at: HRSA, GAC, 1815 N. Fort Meyer Drive, Suite 300, Arlington, VA 22209, Phone: 1–877–HRSA–123, Fax: 1–877–HRSA–345, E-Mail: hrsagac@hrsa.gov

FOR FURTHER INFORMATION CONTACT: For further information contact Dr. Marcia Brand, Health Resources and Services Administration, Parklawn Building, Room 11–25, 5600 Fishers Lane, Rockville, MD 20857, Phone: (301) 443–4619, Fax: (301) 443–0643.

SUPPLEMENTARY INFORMATION: In 1998, 44.5 million people in the United States did not have health insurance. This is roughly one out of every six non-elderly Americans. Of these, 24.6 million were employed—18.7 million worked full time and 5.9 million worked part time. Nationally, over 11 million children (i.e., one in seven) are uninsured. Every year, approximately a million Americans lose their health coverage. A poll conducted for Health Coverage 2000 and released in October showed that seven out of ten Americans believe government must address the problem of the uninsured and state that they support $100 in new taxes to help provide additional health coverage. There is considerable public and private support for examining and implementing new models for providing access to affordable health coverage.

Many States have expressed interest in expanding coverage for the uninsured. Every State has responded to the opportunity provided by the State Children's Health Insurance Program (SCHIP) to design a program that provides health insurance coverage for uninsured low-income children. Many States have also expanded Medicaid coverage to uninsured children and adults, using existing options, such as section 1115 waiver authority, as well as increased flexibility under welfare reform to cover working parents. In addition, many States are assessing State policy in light of recent changes in Medicare. Some States are working towards enhancing coordination of publicly-funded health programs, such as health departments and community health centers. States have also undertaken activities that seek to expand insurance coverage through mechanisms other than Federally-