

composition, number of pregnant and/or parenting adolescent clients, infants, male partners, family members and community members. [Healthy People 2010 is a set of health objectives for the Nation to achieve over the first decade of the new century. The two goals of Healthy People 2010 are to increase quality of years of healthy life and to eliminate health disparities. In evaluating this criterion, priority will be given to programs who serve minority populations in order to eliminate health disparities.] (15 points)

(4) The applicant's presentation of a detailed evaluation plan, indicating an understanding of program evaluation methods, and reflecting a practical and technically sound approach to assessing the project's achievement of program objectives. (15 points)

(5) The applicant's presentation of the need for the project, including the incidence of adolescent pregnancy in the geographic area to be served and the availability of services for adolescents within this geographic area. (10 points)

(6) The applicant's presentation of an organizational model for service delivery with appropriate design, consistent with the requirements of Title XX. (10 points)

(7) The community commitment to and involvement in planning and implementation of the project, as demonstrated by letters of commitment and willingness to participate in the project's implementation, acceptance of referrals, etc. (10 points)

Final grant award decisions will be made by the Deputy Assistant Secretary for:

Population Affairs. In making these decisions, the Deputy Assistant Secretary for Population Affairs will take into account the extent to which grants recommended for approval will provide an appropriate geographic distribution of resources, the priorities in section 2005(a) of Title XX, and the other factors including consideration of:

1. Recommendations and scores submitted by the review panels;
2. The geographic area to be served, particularly the needs of rural areas;
3. The reasonableness of the estimated cost of the project based on factors such as the incidence of adolescent pregnancy in the geographic area to be

served and the availability of services for adolescents in this geographic area;

4. The usefulness for policymakers and service providers of the proposed project and its potential for replication.

Applicants will be notified by letter of the outcome of their applications, after final funding decisions are made. The official document notifying an applicant that an application has been approved for funding is the Notice of Grant Award, which specifies to the grantee the amount of money awarded, the purpose of the grant, the terms and conditions of the grant award, and the amount of funding to be contributed by the grantee to project costs.

Dated: March 2, 2001.

Mireille B. Kanda,

Acting Director for Population Affairs.

[FR Doc. 01-6058 Filed 3-9-01; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards and Security.

Times and Dates: 9 a.m. to 5 p.m., March 19, 2001; and 9 a.m. to 5 p.m., March 20, 2001.

Place: Room 505A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The purpose of this hearing is for NCVHS to obtain public input for the process of making recommendations to the HHS Secretary about specific standards for Patient Medical Record Information (PMRI). The process will include developing (1) criteria for the selection of PMRI message format standards for recommendation to the HHS Secretary, (2) a draft set of questions to PMRI standards developers which is intended to assist the NCVHS select PMRI standards, (3) a proposed list of PMRI transactions that may be considered in the first phase for recommendation to the HHS Secretary, and (4) making any additional comments or critiques about this process.

Notice: In the interest of security, the Department has instituted stringent procedures for entrance to the Hubert H. Humphrey building by non-government employees. Thus, persons without a government identification card will need to have the guard call for an escort to the meeting.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from J. Michael Fitzmaurice, Ph.D., Senior Science Advisor for Information Technology, Agency for Health Care Research and Quality, 2101 East Jefferson Street, #600, Rockville, MD 20852, phone: (301) 594-3938; or Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS website: <http://www.ncvhs.hhs.gov/> where an agenda for the meeting will be posted when available.

Dated: March 2, 2001.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 01-5972 Filed 3-9-01; 8:45 am]

BILLING CODE 4151-05-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: The OCSE-157 Child Support Enforcement Annual Data Report.

OMB No.: 0970-0177.

Description: The information obtained from this form will be used to report Child Support Enforcement activities to the Congress as required by law, to complete incentive measure and performance indicators utilized in the program, and to assist the Office of Child Support Enforcement in monitoring and evaluating State Child Support Enforcement programs.

Respondents: State, Local and Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
OCSE-157	54	1	4	216
Estimated Total Annual Burden Hours				216

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF 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 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 6, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01-5971 Filed 3-9-01; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 00M-1640, 00M-1664, 00M-1591, 00M-1613, 00M-1597, 00M-1593, 00M-1583, 00M-1615, 00M-1612, 00M-1569, 00M-1658, 00M-1570, 00M-1616, 00M-1659, 00M-1649, 00M-1650, 00M-1660, 00M-1661, 00M-1683, 00M-1684]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMA's) that have been approved. 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: Submit a written request for copies of summaries of safety and effectiveness 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 listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT:

Think X. Nguyen, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

SUPPLEMENTARY INFORMATION:

I. Background

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**. Instead, 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 at <http://www.fda.gov> on the Internet; 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)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), 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 October 1, 2000, through December 31, 2000. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE OCTOBER 1, 2000, THROUGH DECEMBER 31, 2000

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970053/00M-1640	Nidek Technologies, Inc.	EC-5000 Excimer Laser System	December 17, 1998
P970053(S1)/00M-1664	Nidek Technologies, Inc.	EC-5000 Excimer Laser System (PARK)	September 29, 1999
P930034(S13)/00M-1591	Summit Technologies	SVS Apex Plus Excimer Laser Workstation	October 21, 1999
P990019/00M-1613	DUSA Pharmaceuticals, Inc.	BLU-U Light Photodynamic Therapy Illuminator	December 3, 1999