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: Thinh 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

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

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P990027/00M–1597	Bausch & Lomb Surgical, Inc.	Technolas® 217 Excimer Laser System	February 23, 2000
P970043(S5)/00M–1593	Autonomous Technologies Corp.	LADAR Vision® Excimer Laser System	May 9, 2000
P990052/00M–1583	Symphonix Devices, Inc.	Vibrant P/Vibrant D Soundbridge System	August 31, 2000
P980010/00M–1615	Osteometer MediTech, Inc.	DTU–One Ultrasound Scanner	September 19, 2000
P970043(S7)/00M–1612	Autonomous Technologies Corp.	LADAR Vision® Excimer Laser System	September 22, 2000
P990040/00M–1569	Cordis Neurovascular, Inc.	Trufill N–Butyl Cyanoacrylate Liquid Embolic System	September 25, 2000
P000014/00M–1658	Ortho–Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Anti-HBS Reagent Pack and Calibrators	September 29, 1999
P990046/00M–1570	ATS Medical, Inc.	ATS Open Pivot® Bileaflet Heart Valve	October 13, 2000
N18286(S12)/00M–1616	Pharmacia & Upjohn Co.	Gelfoam® Sterile Powder	October 16, 2000
P000015/00M–1659	Cochlear Corp.	Nucleus 24 Auditory Brainstem Implant (ABI) System	October 20, 2000
P000018/00M–1649	Novoste Corp.	Beta-Cath™ System	November 3, 2000
P990036/00M–1650	Cordis Corp.	Cordis Checkmate™ System	November 3, 2000
P990056/00M–1660	Roche Diagnostics, Corp.	Elecsys® Total PSA Immunoassay and Calset	November 22, 2000
P990081/00M–1661	Ventana Medical Systems, Inc.	Pathway™ HER 2	November 28, 2000
P000027/00M–1683	Roche Diagnostics Corp.	Elecsys® Free PSA Immunoassay/Calset/Calcheck	December 12, 2000
P980020/00M–1684	Q Care International, LLC	Q–103 Needle Management Systems	December 21, 2000

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: March 1, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–5954 Filed 3–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0056]

Draft Guidance for Industry on Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines.'' This draft guidance is intended to assist applicants and other responsible parties in fulfilling FDA's postmarketing safety reporting requirements for marketed human drugs and biological products.

DATES: Submit written comments on the draft guidance by May 11, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Min C. Chen, Center for Drug Evaluation and Research (HFD–430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3169.

For information concerning human biological products: Miles M. Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3974.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines.'' This draft guidance discusses postmarketing safety reporting requirements for prescription drugs marketed for human use without an approved application § 310.305 (21 CFR 310.305), human drugs with approved new drug applications (NDA) § 314.80 (21 CFR 314.80), human drugs with approved abbreviated new drug applications (21 CFR 314.98), and human biological products with approved biologics license applications (BLA) §§ 600.80 and 600.81 (21 CFR 600.80 and 600.81).

This draft guidance does not apply to in vitro diagnostic products, whole blood or its components, or product manufacturing defects (unless the defect is associated with an adverse experience in humans). Moreover, it does not discuss the following: Investigational new drug application safety reports (21 CFR 312.32), safety update reports for drugs (21 CFR 314.50(d)(5)(vi)), approved NDA annual reports (21 CFR 314.81(b)(2)), or approved BLA annual reports (21 CFR 601.28).

Currently, FDA has three guidances for industry on postmarketing safety reporting: ''Guideline for Postmarketing Reporting of Adverse Drug Experiences'' (March 1992), ''Guideline for Adverse Experience Reporting for Licensed Biological Products'' (October 1993), and ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report'' (August 27, 1997). This draft guidance for industry consolidates the three existing guidances into a single document and revises the information contained within them to be consistent with the final rulemaking described below.

FDA has undertaken a major effort to clarify and revise its regulations regarding pre- and postmarketing safety reporting requirements for human drug and biological products. With regard to the postmarketing expedited safety reporting regulations for human drug