Dated: March 23, 2000.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–7813 Filed 3–29–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Scientific Panel for Immunization Measurement Standards, 2000: Meeting

Name: National Scientific Panel for Immunization Measurement Standards, 2000.

Time and Date: 8 a.m.–5 p.m., May 1, 2000.

Place: Atlanta Marriott Century Center, 2000 Century Boulevard, NE., Atlanta, Georgia 30345–3377.

Status: Open to the public, limited only by the space available.

Purpose: There are two systems for measuring immunization coverage that are widely used. The Health Plan Employer Data and Information Set (HEDIS) measures quality of health care delivered by managed care organizations (MCOs) and enables comparisons of performance among MCOs. The National Immunization Survey (NIS) is a population-based survey of immunization coverage, conducted by CDC to assess how well children are immunized in the US. The inclusion of different vaccines and different measurement criteria has made direct comparison inaccurate and difficult. The Panel will review scientific and programmatic issues concerning immunization coverage measurement.

Matters To Be Discussed: The agenda will include discussion on the impact of various measurement specifications for calculating immunization coverage levels using NIS and HEDIS; the potential impact of various definitions of up-to-date immunization status in the two systems of immunization coverage measurement varying: (1) Age at ascertainment, (2) spacing criteria, (3) number of doses, (4) vaccines in combination measures; presentation of results of analysis of NIS data and datasets used for HEDIS estimates; consideration other ways to estimate vaccine coverage.

Contact Person for More Information: Mehran S. Massoudi, Senior Staff Epidemiologist, Immunization Services Division, National Immunization Program, CDC,1600 Clifton Road, NE., m/s E52, Atlanta, Georgia 30333. Telephone 404/639–8209.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 23, 2000.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–7815 Filed 3–29–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99M–4361, 99M–4277, 99M–4693, 99M–4278, 99M–4276, 99M–4281, 99M–4331, 99M–4279, 99M–4280, 99M–4776, 00M–0578, 99M–4330, 99M–4810, 99M–4692, 99M–5135, 99M–5327, and 99M–5539]

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/pmapage.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**. 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 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 October 1, 1999, through December 31, 1999. 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, 1999, THROUGH DECEMBER 31, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970010/99M–4361	Synthes (USA)	Norian Skeletal Repair System (SRS) Cancellous Bone Cement	December 23, 1998
P970015/99M–4277	Sofamor Danek	Inter Fix Threaded Fusion Device	May 14, 1999
P960033/99M–4693	Staar Surgical	Staarvisc™ Sodium Hyaluronate	July 2, 1999
P980053/99M–4278	Advanced Uroscience, Inc.	Durasphere Injectable Bulking Agent	September 13, 1999
P990008/99M–4276	Cook, Inc.	Cook MBC PTCA Balloon Dilatation Catheter	September 27, 1999
P990001/99M–4281	Vitatron, Inc.	Diva Platform Implantable Pulse Generators & Pro Vit Application Software Version 3.3.2	September 27, 1999
P990020/99M–4331	Medtronic Aneurx	Aneurx Stent Graft System	September 28, 1999
P980043/99M–4279	Medtronic, Inc.	Hancock II Bioprosthetic Heart Valve	September 28, 1999
P990017/99M–4280	Guidant Cardiac & Vascular Surgery	EVT Abdominal Aortic Tube/EVT Abdominal Aortic Bifurcated EGS System	September 28, 1999
P990004/99M–4776	Ethicon, Inc.	Surgifoam Absorbable Gelatin Sponge, USP	September 30, 1999
P940034 (S008)/99M–4782	Gen-Probe, Inc.	Gen-Probe® Amplified Mycobacterium Tuberculosis Direct Test (MTD Test)	September 30, 1999
P990002/99M-4330	Rochester Medical Corp.	Femsoft Urethral Insert	September 30, 1999
H980007/99M–4810	Shelhigh, Inc.	Shelhigh Pulmonic Valve Conduit Model NR–4000 with ''No-React®'' Treatment	September 30, 1999
P990033/99M–4692	Ceramed Corp.	PepGen P–15	October 25, 1999
P990014/99M–5135	Bausch & Lomb Surgical, Inc.	Hydroview Composite Hydrogel Foldable UV–Absorbing Posterior Chamber Intraocular Lens	November 12, 1999
H990007/99M–5327	CryoLife, Inc.	BioGlue® Surgical Adhesive	December 7, 1999
H980006/99M–5539	MDS Nordion, Inc.	TheraSphere®	December 10, 1999

Dated: March 14, 2000.

Linda S. Kahan,

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

[FR Doc. 00–7780 Filed 3–29–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1197]

Guidance for Industry on Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' The purpose of this guidance is to inform the public of FDA's application of the abbreviated new drug application (ANDA) approval provisions and 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on these issues.

DATES: Submit written comments on the guidance by June 28, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Virginia G. Beakes, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' This guidance is being issued in response to recent litigation. The guidance is intended to provide information to the pharmaceutical industry regarding: (1) The timing of approval of ANDA's following an unsuccessful patent infringement action by the patent owner or new drug application (NDA) holder and (2) the start of 180 days of generic drug exclusivity.

FDA's interpretation of two provisions of the act have been successfully challenged in *TorPharm, Inc.* v. *Shalala* and *Mylan Pharmaceuticals, Inc.* v. *Shalala* [1].

[1] *Torpharm* v. *Shalala*, No. 97–1925, 1997 U.S. Dist. LEXIS 21983 (D.D.C. September 15, 1997); *appeal withdrawn and remanded*, 1998 U.S. App. LEXIS 4681 (D.C. Cir. February 5, 1998); *vacated* No. 97–1925 (D.D.C. April 9, 1998); *Mylan*