

Dated: March 23, 2000.

John Burckhardt,

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

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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.

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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/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**. 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.