• Develops, evaluates and maintains policies, regulations, and instructions that define the scope of benefits and payment amounts for:

1. Hospitals for inpatient services under the inpatient prospective payment system and the long-term care hospital prospective payment system;
2. Inpatient services in hospitals and units excluded from the prospective payment systems;
3. Physicians and non-physician practitioners;
4. Hospital outpatient departments, comprehensive outpatient rehabilitation facilities and ambulatory surgical centers;
5. Clinical laboratory services;
6. Ambulance services;
7. Prescription drugs and blood, blood products and hemophilia clotting factor; and
8. Telemedicine services, rural health clinics, and federally-qualified health centers.

• Formulates CMS policy for development, analysis, and maintenance of new and revised medical codes and medical classification systems (including ICD–9–CM, Healthcare Common Procedure Coding System, Diagnosis Related Groups, and Ambulatory Payment Classifications) and develops common medical coding standards and policy.

• Participates in the development and evaluation of proposed legislation pertaining to assigned subject areas.

• Coordinates with the Office of Clinical Standards and Quality on coverage issues in assigned areas.

• Develops, evaluates, and reviews regulations, manuals, program guidelines, and instructions required for the dissemination of program policies to program contractors and the health care field.

• Identifies, studies and makes recommendations for modifying Medicare policies to reflect changes in beneficiary health care needs, program objectives, and the health care delivery system.

• Develops, evaluates and maintains policies, regulations, and instructions that define the scope of benefits and payment amounts for skilled nursing facilities, home health agencies, hospice, durable medical equipment, orthotics, prosthetics and supplies.

• Develops and evaluates national Medicare policies and principles for applying limitations to the costs of skilled nursing facilities and home health agencies. Develops criteria for exceptions to the cost limitations for skilled nursing facilities. Reviews and makes decisions on requests for such exceptions.

• Analyzes payment data, develops, maintains and updates payments rates for End Stage Renal Disease services and Program of All-Inclusive Care for the Elderly sites.

• Manages designation process for Medicare organ transplant centers, organ procurement organizations and for hospitals seeking out-of-service-area waivers.

• Develops, issues and administers the specifications, requirements, methods, standards, policies, procedures and budget guidelines for Medicare claims processing related activities, including detailed definitions of the relative responsibilities of providers, contractors, CMS, other third-party payers and the beneficiaries of the Medicare program.

• Develops and releases the coding and pricing databases and software for physician, laboratory, Skilled Nursing Facility, Home Health, Inpatient, Outpatient and supplier services in the Medicare claims processing standard systems.

• Develops policies related to the integration of health care services, including policies on ownership and referral arrangements, business relationships and conflict of interest.

• Serves as the CMS lead for management, oversight, budget and performance issues relating to Medicare carriers, fiscal intermediaries, and MACs.

• Functions as CMS liaison for all Medicare carrier, fiscal intermediary, and MAC program issues and, in close collaboration with the regional offices and other CMS components, coordinates Agency-wide contractor activities.

• Manages contractor instructions, workload, and change management process.

• Manages and oversees Medicare contractor provider inquiry, outreach, and education activities including specifying Budget Performance Requirements, allocating and managing budget dollars across contractors, evaluating supplemental budget requests, issuing program instructions and participating in contractor performance evaluation activities.

• In conjunction with the CMS program area experts, develops training programs and materials, and training tools to educate providers, physicians, suppliers and Medicare contractor provider education staff on new initiatives and changes to the Medicare program.

• Develops national provider/supplier education products and training tools for Medicare contractors as well as for provider education provided directly by CMS.

• Supports communication between CMS and the provider/supplier community through facilitation of ''open door'' and Participating Physician Advisory Committee meetings, other listening sessions and promotes awareness of Agency initiatives by sponsoring exhibit programs at industry conferences.

• Develops system requirements and computer software for select portions of Medicare FFS claims processing systems.

• Develops and implements Medicare FFS program requirements for provider billing and for claims processing systems.

• Implements the Medicare Health Support Program.

Dated: September 18, 2008.

**James W. Weber,**

*Acting Director, Office of Operations Management, Centers for Medicare & Medicaid Services.*

[FR Doc. E8–22690 Filed 9–25–08; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2008–D–0514]**

### Draft Guidance for Industry on End-of-Phase 2A Meetings; 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 ''End-of-Phase 2A Meetings.'' This draft guidance provides information on end-of-phase 2A (EOP2A) meetings for sponsors of investigational new drug applications (INDs) who seek guidance on employing clinical trial simulation and quantitative modeling of prior knowledge (e.g., drug, disease, placebo) to design trials for better dose response estimation, dose selection, and other appropriate issues. This draft guidance is intended to further FDA initiatives directed at identifying opportunities to facilitate the development of innovative medical products and to improve the quality of drug applications through early meetings with sponsors.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

written or electronic comments on the draft guidance by November 25, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Robert Powell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4526, Silver Spring, MD 20993–0002, 301–796–1589

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''End-of-Phase 2A Meetings.'' This draft guidance will meet one of the performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV). Under section XI of the PDUFA IV Performance Goals, Expediting Drug Development, FDA agreed to publish by the end of fiscal year 2008 a draft guidance on end-of-phase 2A meetings (see section XI.A.4 at *http://www.fda.gov/oc/pdufa4/pdufa4goals.html*). This draft guidance is intended to facilitate early meetings (referred to as end-of-phase 2A meetings or EOP2A meetings) between FDA and sponsors who seek interaction or guidance related to the use of quantitative drug development methods (i.e., exposure-response, pharmacokinetic/pharmacodynamic (PK/PD) modeling, drug-disease modeling, genomic analysis) to inform drug development and regulatory decisions. The draft guidance provides recommendations to IND sponsors on the following topics:

- Objectives of an EOP2A meeting,
- Possible topics for discussion at EOP2A meetings,
- Useful information for an EOP2A meeting package, and
- Timing of EOP2A meetings.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on end-of-phase 2A meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 and the guidance on ''Formal Meetings With Sponsors and Applicants for PDUFA Products'' have been approved under OMB control numbers 0910–0014 and 0910–0429, respectively.

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: September 22, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–22669 Filed 9–25–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2008–M–0207, FDA–2008–M–0243, FDA–2008–M–0244, FDA–2008–M–0283, FDA–2008–M–0335, FDA–2008–M–0311, FDA–2008–M–0342, FDA–2008–M–0378]**

### 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 (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (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 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:** Nicole Wolanski, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4010.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. 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