approval prior to distribution of the product made using the change (major changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as the factors may relate to the safety or effectiveness of the product. The applicant must obtain approval of a supplement from FDA prior to distribution of a product made using the change.

Based on data concerning the number of supplements received by the agency, FDA estimates that approximately 1,744 supplements will be submitted annually under section 506A(c)(1) and (c)(2) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 120 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act sets forth requirements for changes requiring supplement submission at least 30 days prior to distribution of the product made using the change (moderate changes). Under this section, a supplement must be submitted for any change in the product, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity or potency of the product as these factors may relate to the safety or effectiveness of the product. Distribution of the product made using the change may begin not less than 30 days after receipt of the supplement by FDA.

Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 2,754 supplements will be submitted annually under section 506A(d)(1)(B), (d)(1)(C), and (d)(3)(B)(i) of the act. FDA estimates that approximately 594 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Under section 506A(d)(3)(B)(ii) of the act, FDA may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug upon receipt by the agency of a supplement for the change. Based on the data concerning the number of supplements received by the agency, FDA estimates that approximately 486 supplements will be submitted annually under section 506A(d)(3)(B)(ii) of the act. FDA estimates that approximately 486 applicants will submit such supplements, and that it will take approximately 80 hours to prepare and submit to FDA each supplement.

Section 506A(d)(1)(A), (d)(1)(C), and (d)(2)(A), and (d)(2)(B) of the act sets forth requirements for changes to be described in an annual report (minor changes). Under this section, changes in the product, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as these factors may relate to the safety or effectiveness of the product must be documented by the applicant in the next annual report.

Based on the data concerning the number of supplements and annual reports received by the agency, FDA estimates that approximately 6,929 annual reports will include documentation of certain manufacturing changes as required under section 506A(d)(1)(A), (d)(1)(C), (d)(2)(A), and (d)(2)(B) of the act. FDA estimates that approximately 704 applicants will submit such information, and that it will take approximately 25 hours to prepare and submit to FDA the information for each annual report.

In the **Federal Register** of June 28, 1999 (64 FR 34608), FDA published a proposed rule to implement section 116 of the Modernization Act by revising current regulations at 21 CFR 314.70 on supplements and other changes to an approved application. In that same issue of the **Federal Register** (64 FR 34660), FDA published a notice of availability of a draft guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' On August 19, 1999, FDA held a public meeting to discuss and receive comments on the proposed regulations and the draft guidance (64 FR 42625, August 5, 1999).

The period for public comment on the proposed regulations closed on September 13, 1999 and FDA is currently reviewing the comments and preparing a final rule. The comment period for the draft guidance closed on August 27, 1999, and FDA has considered these comments when preparing the guidance that is the subject of this request.

FDA published in the **Federal Register** of January 6, 2000 (65 FR 779), a 60-day notice requesting comments on the extension of the proposed collection of information in this guidance. In response to this notice, no comments were received by the agency.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: March 30, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–8599 Filed 4–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Opthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 11, 2000, 9:30 a.m. to 5 p.m., and May 12, 2000, 8:30 a.m. to 5 p.m.

Location: Hilton Hotel, Salons A and B, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, SMT@CDRH.FDA.GOV, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 11, 2000, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for reduction or elimination of hyperopia (+0.5 to +5.00 diopters of sphere) with astigmatism (+0.5 to +4.0 diopters of cylinder) using photorefractive keratectomy (PRK).

On May 12, 2000, the committee will discuss issues related to the design and development of clinical protocols to support claims of reduced posterior capsular opacification (PCO) for intraocular lenses (IOL's). The topics for discussion will include study,

methodology, controls, clinical endpoints, and data analysis. The committee will also discuss issues related to the development of guidance for refractive implants (phakic IOL's and corneal implants). The topics for discussion will include the scope of the proposed guidance, the maintenance of endothelial cell counts, and cataractogenesis due to the presence of an implant. As the materials become available, background information, questions for the panel, a bibliography for the PCO discussion, and an overview of the proposed clinical study section and questions for the panel for the refractive implants discussion will be made available to the public on FDA's website at http://www.fda.gov/ohrms/dockets/ac/cdrh00.htm#ophthalmicdevices.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 1, 2000. Oral presentations from the public will be scheduled between approximately 9:15 a.m. and 9:45 a.m. on May 11, 2000, and between approximately 8:45 a.m. and 9:15 a.m. on May 12, 2000. On May 11, 2000, near the end of the committee deliberations on the PMA, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 1, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–8600 Filed 4–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1128–N]

RIN 0938–AK01

Medicare Program; Process for Requesting Recognition of New Technologies and Certain Drugs, Biologicals, and Medical Devices for Special Payment Under the Hospital Outpatient Prospective Payment System

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: We expect to implement a prospective payment system for hospital outpatient services for the Medicare program on July 1, 2000. This system will recognize new technology as discrete payment groups within the ambulatory payment classification (APC) system. This payment system will also provide for additional payments to hospitals at amounts higher than the amounts that would otherwise be paid for certain specified items, such as: orphan drugs; drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; radiopharmaceutical drugs and biologic products; and certain new or innovative medical devices. We have identified items or services for inclusion in the new technology APC groups, as well as items potentially eligible for special additional payments. This notice addresses the process that interested parties must use to submit additional items for consideration.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786–3355.

SUPPLEMENTARY INFORMATION: We expect to implement a prospective payment system (PPS) for hospital outpatient services for Medicare on July 1, 2000. One aspect of this system will be to develop a process to recognize new technologies on an ongoing basis in a timely manner, and to establish special payments for a number of specified items, in accordance with section 201 of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), enacted on November 29, 1999. New technologies refer to services and items that have emerged since 1996, and therefore are not reflected in the cost data that are being used to develop our PPS. Additionally, section 201(b) of the BBRA requires us to make additional payments to hospitals for a period of 2 to 3 years for specific items at amounts higher than the amounts that would otherwise be paid under the hospital outpatient PPS for items in the following categories: (a) current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; (b) current drugs, biologic agents, and brachytherapy devices used for the treatment of cancer; (c) current radiopharmaceutical drugs and biologicals; and (d) new or innovative medical devices, new drugs, and biologic agents, in instances when we were not paying for the item as a hospital outpatient service as of December 31, 1996, and when the cost is ''not insignificant'' in relation to the hospital outpatient PPS payment amount. In this context, ''current'' refers to those items for which we are making hospital outpatient payment on the first date the new PPS is implemented.

We will include these items and services within payment groups called ambulatory payment classifications (APCs), which will be used in the payment system for hospital outpatient services. In addition to the APC-related payments, however, hospitals may receive additional payment for specified items. In order to appropriately assign items to the new technology APCs and make special payments for the relevant drugs, biologicals, and medical devices, we must be able to identify the specific items and services, and ensure that HCFA Common Procedure Coding System (HCPCS) codes are established for them. To facilitate this activity, we have placed on our Internet site at *http://www.hcfa.gov/medicare/hopsmain.htm* the following information:

(a) A list of those items and services that we have already identified as potentially eligible for special payments or treatment as a new technology service; and

(b) The procedures interested parties must follow to bring to our attention additional items that may be eligible.

If you cannot access this information on our Internet site, you may request a paper copy by contacting Joan Briscoe in the Division of Practitioner and Ambulatory Care at (410) 786–4495.

Authority: Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 21, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: March 31, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–8744 Filed 4–6–00; 8:45 am]

BILLING CODE 4120–01–P