III. Regulatory Impact Statement

[If you choose to comment on issues in this section, please include the caption ''Regulatory Impact Statement'' at the beginning of your comments.]

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We have determined that this notice is not a major rule. The States' FY 2002 SCHIP allotments, totaling $3,115,200,000 were originally published in a notice in the **Federal Register** and allotted to States in FY 2002. This notice with comment period does not revise the amount of the 2002 allotment originally made available to the States, but rather, sets forth the procedure for redistributing those FY 2002 allotments, which were unexpended at the end of FY 2004 (the end of the 3-year period of availability referenced in section 2104(e) of the Act), and announces the amount of the FY 2002 allotments to be redistributed to the redistribution States and the availability of such unexpended FY 2002 allotment amounts to the end of 2005. Because participation in the SCHIP program on the part of States is voluntary, any payments and expenditures States make or incur on behalf of the program that are not reimbursed by the Federal Government are made voluntarily. This notice will not create an unfunded mandate on States, tribal, or local governments. Therefore, we are not required to perform an assessment of the costs and benefits of this notice.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice and have determined that it does not significantly affect States' rights, roles, and responsibilities.

Low-income children will benefit from payments under this program through increased opportunities for health insurance coverage. We believe this notice will have an overall positive impact by informing States, the District of Columbia, and Commonwealths and Territories of the extent to which they are permitted to expend funds under their child health plans using the FY 2002 allotment's redistribution amounts.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

IV. Waiver of Notice of Proposed Rulemaking and Delayed Effective Date

[If you choose to comment on issues in this section, please include the caption ''Waiver of Notice of Proposed Rulemaking and Delayed Effective Date'' at the beginning of your comments.]

We ordinarily publish a proposed notice in the **Federal Register** to provide a period of public comment before the provisions of a notice, such as this, are effective in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). We also ordinarily provide a 30-day delay in the effective date of the provisions of a notice in accordance with section 553(d) of the APA (5 U.S.C 553(d)). However, we can waive both the notice of proposed rulemaking and the 30-day delay in effective date if the Secretary finds, for good cause, that it is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the notice.

We find there is good cause to waive notice of proposed rulemaking and the delay in the effective date of this issuance of the FY 2002 redistributed allotments because such notice of proposed rulemaking and the delay in the effective date would be contrary to the public interest.

We determined the amounts of the FY 2002 redistributed allotments as expeditiously as possible in order to make them available to the States as soon as possible. To that end, all States had until November 30, 2004 to submit their required fourth quarter FY 2004 expenditure reports. In determining the FY 2002 redistributed amounts, we used State projected expenditures as contained in the most recent (November, 2004) States' quarterly budget report submissions. The redistributed FY 2002 allotments make available Federal funds to the recipient redistribution States, which is especially important for those redistribution States that may need such funds.

Furthermore, under section 2104(e) of the Act, redistributed allotments are only available through the end of the fiscal year in which they are redistributed; in the case of the FY 2002 redistributed allotments, that would be until the end of FY 2005 (September 30, 2005). We believe it is important that we issue these redistributed allotments as soon as possible. Therefore, in the interest of ensuring that the FY 2002 redistributed allotments are made available without delay to those States that need such funds, we are waiving notice of proposed rulemaking and the 30-day delay in effective date, and are publishing this issuance of the **Federal Register** as a notice with comment period.

Accordingly, we provisionally will make the FY 2002 redistributed funds available to any State that has spent all of its available SCHIP allotments effective immediately upon publication of this notice with comment period. These FY 2002 redistributed funds are subject to final adjustment based on comments received in response to this notice with comment period. Any such adjustments resulting from review and analysis of comments will be published in the **Federal Register** within 60 days of the close of the comment period. (Section 1102 of the Social Security Act (42 U.S.C. 1302).)

(Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program)

Dated: January 5, 2005.

Mark McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 14, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–1139 Filed 1–18–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0559]

Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management 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 Committees: Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on February 16, 2005, from 8 a.m. to 6 p.m., and on February 17 and 18, 2005, from 8 a.m. to 5 p.m.

Addresses: Electronic comments should be submitted to *http://www.fda.gov/dockets/ecomments*. Select ''2004N–0559—Overall Benefit to Risk Considerations for COX-2 Selective Nonsteroidal Anti-inflammatory Drugs and Related Agents'' and follow the prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments received by February 4, 2005, will be provided to the committee before the meeting.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Kimberly Littleton Topper or Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301–827–7001, FAX: 301–827–6801, e-mail: *topperk@cder.fda.gov* or *spelllesaned@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512532 or 3014512535. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will discuss the overall benefit to risk considerations (including cardiovascular and gastrointestinal safety concerns) for COX-2 selective nonsteroidal anti-inflammatory drugs and related agents. The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the headings ''Arthritis Advisory Committee'' or ''Drug Safety and Risk Management Advisory Committee'' (click on the year 2005 and scroll down to the above named committee meetings).

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 Division of Dockets Management (see *Addresses*). Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on February 17, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 4, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Tony Slater at 301–827–7001, at least 7 days in advance of the meeting.

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

Dated: January 11, 2005.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–958 Filed 1–18–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Transmissible Spongiform Encephalopathies 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: Transmissible Spongiform Encephalopathies 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 February 8, 2005, from 8 a.m. to 5:30 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512392. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following: (1) Risk assessments for potential exposure to the variant Creutzfeldt-Jakob disease (vCJD) agent in plasma products, (2) possible vCJD risk from investigational coagulation Factor XI manufactured in the 1990s from plasma of donors residing in the United Kingdom, and (3) potential deferral of blood and plasma donors for history of transfusion in France and other European countries.

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 February 1, 2005. Oral presentations from the public will be scheduled between approximately 11:50 a.m. and 12:30 p.m., 3:15 p.m. and 3:30 p.m., and 4:15 p.m. and 4:35 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 3, 2005, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact William Freas or Sheila D. Langford at least 7 days in advance of the meeting.

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