DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1595]

Draft Guidance for Industry on Recommendations for Complying With the Pediatric Rule; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)).'' The draft guidance provides recommendations for sponsors of new drug applications (NDA's) and biologics license applications (BLA's) on how to meet the requirements of the final rule requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients (pediatric rule).

DATES: Submit written comments on the draft guidance by March 5, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm.* Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Terrie L. Crescenzi, Center for Drug Evaluation and Research (HFD–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, FAX 301–827–2520, e-mail *crescenzit@cder.fda.gov*, or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0641, FAX 301–827–0644, e-mail *esber@cber.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Recommendations for Complying With the Pediatric Rule (21 CFR 314.55(a) and 601.27(a)).'' In the **Federal Register** of December 2, 1998 (63 FR 66632), FDA published the pediatric rule. Under the pediatric rule, applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration must contain a pediatric assessment unless the applicant has obtained a waiver or deferral of pediatric studies (21 CFR 314.55(a) and 601.27(a)). The rule became effective on April 1, 1999. Under the compliance dates in the final rule, pediatric assessments must be included in applications after December 2, 2000, for: (1) NDA's; (2) BLA's; and (3) abbreviated new drug applications (ANDA's) that are based on suitability petitions for a change in active ingredient, dosage form, or route of administration.[1] This draft guidance describes how the pediatric rule will be implemented. Areas covered include an overview of pediatric assessments, pediatric plans, waivers and deferrals, compliance issues, pediatric exclusivity, and the role of FDA's Pediatric Advisory Subcommittee.

This Level 1 draft guidance is being issued consistent with FDA's good guidance regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on how to comply with the pediatric rule. 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.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

[1] On November 4, 1999, FDA received a citizen petition raising issues associated with the relationship between the pediatric rule and ANDA suitability petitions. The issues raised in the petition are still under consideration by the agency. Therefore, this guidance does not address pediatric studies associated with suitability petitions.

Dated: November 22, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–30697 Filed 12–1–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1156–N]

Medicare Program; Request for Nominations for the Practicing Physicians Advisory Council

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

ACTION: Notice.

SUMMARY: This notice requests nominations from physician medical organizations for individuals to serve on the Practicing Physicians Advisory Council.

Section 4112 of the Omnibus Budget Reconciliation Act of 1990 established the Council to advise the Secretary of the Department of Health and Human Services on proposed regulations and manual issuances related to physicians' services. There will be three Council vacancies on February 28, 2001.

EFFECTIVE DATE: Nominations will be considered if we receive them at the appropriate address, provided below, no later than 5 p.m., E.S.T., on December 30, 2000.

ADDRESSES: Mail or deliver nominations to the following address: Health Care Financing Administration, Center for Health Plans and Providers, Office of Professional Relations, Attention: Paul Rudolf, MD, JD, Executive Director, Practicing Physicians Advisory Council, Room 435–H, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Paul Rudolf, MD, JD, Executive Director, Practicing Physicians Advisory Council, (202) 690–7418.

SUPPLEMENTARY INFORMATION: Section 4112 of the Omnibus Budget Reconciliation Act of 1990 (Public Law 101–508) added a new section 1868 to the Social Security Act (the Act), which established the Practicing Physicians Advisory Council (the Council). The Council advises the Secretary of the Department of Health and Human Services (the Secretary) on proposed regulations and manual issuances related to physicians' services. An advisory committee created by the Congress, such as this one, is subject to

the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Section 1868(a) of the Act requires that the Council consist of 15 physicians, each of whom must have submitted at least 250 claims for physicians' services under Medicare in the previous year. At least 11 Council members must be physicians as defined in section 1861(r)(1) of the Act, that is, State-licensed physicians of medicine or osteopathy. The other four Council members may include dentists, podiatrists, optometrists, and chiropractors.

The Council must include both participating and nonparticipating physicians, as well as physicians practicing in rural and underserved urban areas. In addition, section 1868(a) of the Act provides that nominations to the Secretary for Council membership must be made by medical organizations representing physicians.

This notice is an invitation to all organizations representing physicians to submit nominees for membership on the Council. Current members whose terms expire in 2001 will be considered for reappointment, if renominated, subject to the Federal Advisory Committee Management Handbook. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

Each nomination must state that the nominee has expressed a willingness to serve as a Council member and must be accompanied by a short resume or description of the nominee's experience. To permit an evaluation of possible sources of conflict of interest, potential candidates will be asked to provide detailed information concerning financial holdings, consultant positions, research grants, and contracts.

Section 1868(b) of the Act provides that the Council meet once each calendar quarter, as requested by the Secretary, to discuss proposed changes in regulations and manual issuances that relate to physicians' services. Council members are expected to participate in all meetings. Section 1868(c) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, the Department of Health and Human Services provides management and support services to the Council.

Authority: Section 1868 of the Social Security Act (42 U.S.C. 1395ee); 5 U.S.C. App. 2; and 45 CFR part 11.

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

Dated: November 28, 2000.

Michael M. Hash,

Acting Administrator, Health Care Financing Administration.

[FR Doc. 00–30717 Filed 12–1–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds Announced in the HRSA Preview; Correction

AGENCY: Health Resources and Services Administration.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** issue of Friday, July 7, 2000, make the following corrections:

Correction

In the **Federal Register** notice of Friday, July 7, 2000, in Part III ''Availability of Funds Announced in the HRSA Preview'' of FR Doc. 00–16874:

(1) on page 42223, the grant category beginning in the third column under the heading ''Healthy Start Initiative Eliminating Disparities in Perinatal Health (CFDA #93.926E),'' is amended to: (a) further restrict eligibility to applicants who will establish community-based consortia of individuals and organizations (including State Title V agencies, consumers of project services, public health departments, hospitals, community health centers, and other significant sources of health care services) that are appropriate for participation. Eligibility remains open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b); (b) restrict project areas to those which target a geographic area with high annual rates of infant mortality within a particular State, i.e., no statewide programs will be funded and (c) require that grantees coordinate their services and activities with State Title V agencies. Funding priorities and/or preferences will be given only to applicants who were recipients of Healthy Start community-based grants awarded prior to July 2000 (details will be provided in the application guidance). There will be no special considerations. The estimated amount of this competition will be up to $66,840,000. It is anticipated that 67 awards will be made.

(2) on page 42224, the grant category beginning in the first column under the heading ''Interconceptional Care for High-Risk Women and Their Infants (CFDA #93.926K)'', is amended to: (a) further restrict eligibility to applicants who will establish community-based consortia of individuals and organizations (including State Title V agencies, consumers of project services, public health departments, hospitals, community health centers, and other significant sources of health care services) that are appropriate for participation. Eligibility remains open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b); (b) restrict project areas to those which target a geographic area with high annual rates of infant mortality within a particular State, *i.e.,* no statewide programs will be funded and (c) require that grantees coordinate their services and activities with State Title V agencies. Funding priorities and/or preferences will be given only to applicants who were recipients of Healthy Start community-based grants awarded prior to July 2000 (details will be provided in the application guidance). There will be no special considerations.

(3) on page 42224, the grant category beginning in the second column under the heading ''Improving Women's Health Through Screening and Intervention for Depression During and Around the Time of Pregnancy (CFDA #93.926L)'' is amended to: (a) further restrict eligibility to applicants who will establish community-based consortia of individuals and organizations (including State Title V agencies, consumers of project services, public health departments, hospitals, community health centers, and other significant sources of health care services) that are appropriate for participation. Eligibility remains open to any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b); (b) restrict project areas to those which target a geographic area with high annual rates of infant mortality within a particular State, *i.e.,* no statewide programs will be funded and (c) require that grantees coordinate their services and activities with State Title V agencies. Funding priorities and/or preferences will be given only to applicants who were recipients of Healthy Start community-based grants awarded prior to July 2000 (details will be provided in the application