

Market a New Drug, Biologic, or an Antibiotic for Human Use." The new harmonized form is intended to be used by applicants for all drug and biological products. The new harmonized form, when fully implemented, will allow biological product manufacturers to submit a single application, the BLA, instead of two separate license application submissions, a product license application (PLA), and an establishment license application (ELA).

This draft guidance document represents the agency's current thinking on content and format of the CMC information and establishment description information for biological in vitro diagnostic products. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written comments to the Dockets Management Branch (address above) regarding the draft guidance document. Written comments may be submitted at any time, however, comments should be submitted January 11, 1998, to ensure their adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document by using the World Wide Web (WWW). For WWW access connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: November 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-1048-N]

RIN 0938-AJ27

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 medical organizations representing physicians for individuals to serve on the Practicing Physicians Advisory Council (the 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. Four council members' terms of service are scheduled to expire on February 28, 1999.

EFFECTIVE DATE: Nominations will be considered if we receive them at the appropriate address, provided below, no later than 5 p.m. on November 30, 1998.

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

FOR FURTHER INFORMATION CONTACT: Aron Primack, M.D., 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 1999 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: October 30, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 98-30103 Filed 11-9-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Evaluation of High-Risk Youth Substance Abuse Prevention

Initiatives—0930-0178 (Extension, no change)—The Center for Substance Abuse Prevention (CSAP) is conducting a cross-site evaluation of 47 demonstration projects targeting high-risk youth to assess the effectiveness of the demonstration program in: (1) preventing and/or reducing substance abuse among at-risk youth; and (2) intervention strategies for reducing selected risk factors and enhancing protective factors. Youth participating in the programs and comparison group youth complete self-administered questionnaires at four points in time: baseline; at program exit; 6 months after program exit; and 18 months after program exit. The project annual burden estimate, annualized over the 5-year project period, is shown below:

	Number of respondents	Number of responses/respondent	Average burden/response (hours)	Annualized burden hours
Youth Questionnaires *	11,100	4	.64	4,522
Tracking Form	11,100	1	.05	111
Total				4,633

* Burden estimate based on an average of 45 minutes for baseline and exit questionnaires and 30 minutes for each follow-up questionnaire. Annualized estimates reflect actual attrition rates.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Daniel Chenok, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: November 3, 1998.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 98-30057 Filed 11-9-98; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of Draft Comprehensive Conservation Plan and Environmental Assessment for the Management of Florida Panther National Wildlife Refuge in Collier County, Florida, and Notice of Meeting To Seek Public Comments

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and meeting.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service, Southeast Region, has made available

for public review a draft comprehensive conservation plan for the management of a national wildlife refuge in Collier County, Florida, and plans to hold a public meeting in the vicinity of the refuge to solicit public comments on the draft plan. A copy of the plan is available at local libraries in Collier and Lee counties, Florida. A copy may also be obtained by contacting the Fish and Wildlife Service's Regional Office in Atlanta, Georgia, at the address given below.

DATES: The Service will hold a public meeting on December 5, 1998, 10 a.m. to 6 p.m., at the Fish and Wildlife Service office located in the Comfort Inn, 3860 Tollgate Boulevard, Naples, Florida 34114. In addition, written comments on the draft plan should be sent no later than December 21, 1998, to the address given below.

FOR FURTHER INFORMATION CONTACT: Mr. Charles R. Danner, U.S. Fish and Wildlife Service, Southeast Regional Office, 1875 Century Boulevard, Atlanta, GA 30345 (Telephone 1-800-419-9582).

SUPPLEMENTARY INFORMATION: The refuge covers approximately 26,400 acres and lies within the Big Cypress Swamp physiographic region of Florida. The plan presents three alternatives for the protection and management of the refuge including a "no action" alternative. The refuge's mission is to

conserve and manage lands and waters in concert with other agency land efforts within the Big Cypress Watershed, primarily for the Florida panther, other endangered and threatened species, natural diversity, and cultural resources for the benefit of the American people.

Dated: November 4, 1998.

Sam D. Hamilton,

Regional Director.

[FR Doc. 98-30059 Filed 11-9-98; 8:45 am]

BILLING CODE 4310-55-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

ACTION: Notice of receipt of applications.

SUMMARY: The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(a) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*).

Permit No. TE 003208-0

Applicant: Frances Prevost, Ponchatoula, Louisiana

Applicant requests authorization to purchase in interstate commerce masked bobwhites (*Colinus virginianus*