between approximately 3 p.m. and 5 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 14, 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.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

If you need special accommodations due to a disability, please contact Ms. Toni Fennell, 301–443–7118 at least 7 days in advance.

Dated: June 29, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–17277 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1350]

Draft Guidance for Industry on Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' FDA's Center for Drug Evaluation and Research is issuing this draft guidance for drug products in the combined oral contraceptives class. When finalized, the guidance should result in uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients when they read and try to understand efficacy claims and safety risks associated with drug products in this class. In addition, this draft guidance is intended to provide sponsors of new combined oral contraceptive drug products with a labeling template.

DATES: Submit written comments on the draft guidance by September 8, 2000. 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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lana L. Pauls, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Combined Oral Contraceptives—Labeling for Healthcare Providers and Patients.'' The draft guidance is intended to produce uniform labeling among combined oral contraceptive products. Uniform labeling is important to physicians and patients in understanding efficacy claims and safety risks associated with drug products in this class. The draft guidance, which outlines recommendations for the physician insert, also includes a labeling template for physician labeling and instructions for use that can be used for new drug applications and abbreviated new drug applications. Among the labeling recommendations is a black box warning explaining the increased risk of serious cardiovascular side effects associated with the concomitant use of cigarettes and combined oral contraceptives. Once the draft guidance is finalized, the recommended text should be included in all approved, pending, and future applications. This labeling guidance is intended to supersede the ''Labeling Guidance for Combination Oral Contraceptives, Physician and Patient Labeling,'' revised in August 1994.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on combined oral contraceptive labeling for healthcare providers and patients. 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.

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.

Dated: June 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–17278 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Correction

AGENCY: Health Resources and Services Administration.

ACTION: Notice; correction.

SUMMARY: In the **Federal Register** notice of Monday, June 5, 2000, in FR Doc. 00–13951, on page 35657, beginning in the first column under grant category (2) ''Partnership for State Oral Health Leadership Cooperative Agreement (MCHB),'' reference is made to ''Funding Priorities and/or Preferences: A funding preference will be given to institutions of higher learning with extensive experience in early discharge research, linkage with the Secretary's Advisory Committee on Infant Mortality, and published research and recognition in the relevant field.'' This reference was erroneous and should be corrected to read: ''Funding Priorities and/or Preferences: None.''

FOR FURTHER INFORMATION CONTACT: David Heppel, M.D., Director, Division of Child, Adolescent, and Family Health, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone 1–301–443–2250.

Dated: June 30, 2000.

James J. Corrigan,

Associate Administrator for Management and Program Support.

[FR Doc. 00–17279 Filed 7–7–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Eligibility Criteria for the Centers of Excellence Program in Health Professions Education for Under-represented Minority Individuals

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice requests comments on proposed eligibility criteria for the Center of Excellence (COE) program in health professions education for under-represented minority (URM) individuals. When finalized, these eligibility criteria, will be used to determine the eligibility of designated health professions schools in Fiscal Year 2001. The designated health professions schools are schools of allopathic and osteopathic medicine, dentistry, pharmacy, and graduate programs in behavioral and mental health. The COE program is authorized by section 736 of the Public Health Service Act (the Act) (42 U.S.C. 293).

DATES: Interested persons are invited to comment by August 9, 2000. All comments received on or before August 9, 2000, will be considered in the development of the final eligibility criteria for the COE program. Comments will be addressed individually or by group in the final notice published in the **Federal Register**.

ADDRESSES: All written comments concerning this notice should be submitted to Mario A. Manecci, Acting Director, Division of Health Professions Diversity, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A–09, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Mario A. Manecci, Acting Director, Division of Health Professions Diversity; telephone (301) 443–2100.

SUPPLEMENTARY INFORMATION:

Purpose

The COE program supports programs of excellence in health professions education for under-represented minority (URM) individuals in designated health professions schools. These designated health professions school COE categories are: certain Historically Black Colleges and Universities, Hispanic, Native American, and other health professions schools that meet the program requirements. The COEs are innovative resource and education centers to recruit, train, and retain URM students and faculty at health professions schools. They carry out activities to improve information resources, clinical education, curricula and cultural competence, focusing on minority health issues. The COEs also focus on facilitating faculty and student research on health issues particularly affecting under-represented minority groups. The ultimate goal of the COE program is to strengthen the national capacity to produce a culturally competent healthcare workforce diversity that represents the U.S. population.

Proposed Eligibility Criteria

The Act requires the designated schools to meet each of four general conditions as part of their eligibility requirements. The schools must: (1) Have a significant number of URM students enrolled; (2) have been effective in assisting its URM students to complete the educational program and receive the attached degree; (3) have been effective in recruiting URM students to enroll in and graduate from the school, including providing financial assistance and encouraging URM students at all levels of education to pursue health professions careers; and (4) have made significant recruitments efforts to increase the number of URM students serving in faculty or administrative positions at the school.

The intent of the COE statute is to identify and support institutions with a commitment to URM's and who have attained, as demonstrated by meeting minimum standards, the expertise in recruiting, teaching, training, and retaining the URM health professional, both as practitioners and as faculty. The proposed criterion is to ascertain that eligible institutions have demonstrated progress in improving the school's information resources, clinical education, and curricula and cultural competence of their graduates with respect to minority health issues. The criteria is to ensure that COE applicants will contribute effectively to the attainment of the HRSA goals of increased diversity in the health care workforce and improving the capacity of designated schools to support programs of excellence in health professions education for URMs. Beginning in FY 2001, the Secretary proposes to establish the following criteria to determine these four eligibility conditions.

A. First Condition

The school must have a significant number of URM students enrolled, including students who have been accepted for enrollment at the school. The Secretary will determine the ''significant number'' for Hispanic and Native American COEs based on a percentage of the current number of URM students enrolled in these schools. This determination is unnecessary, however, for Historically Black Colleges and Universities which meet the ''significant number'' condition by virtue of their definition. With respect to the ''other'' COE health professions schools, the Act requires these schools to have a current enrollment of URMs above the national average.

Given the relatively low number of URMs enrolled in health professions schools, a significant number of URMs would be the number that the Secretary views as a critical mass of URM students. The variation in health professions schools class size and total school enrollment also impacts on the determination of the critical mass of URM students. These figures are as follows:

ALLOPATHIC MEDICINE: TOTAL SCHOOLS = 125

Hispanic Significant Number = 20

There are 39 schools (31%) out of 125 with 20 or more Hispanic students enrolled.

Native American Significant Number = 8

There are 24 schools (20%) out of 125 with 8 or more Native American students enrolled.

OSTEOPATHIC MEDICINE: TOTAL SCHOOLS = 19

Hispanic Significant Number = 20

There are 8 schools (40%) out of 19 with 20 or more Hispanic students enrolled.

Native American Significant Number = 5

There are 6 schools (30%) out of 19 with 5 or more Native American students enrolled.

PHARMACY: TOTAL SCHOOLS = 73

Hispanic Significant Number = 20

There are 10 schools (14%) out of 73 with 20 or more Hispanic students enrolled.